

EPA Jacket 2382-189

Material Sent for Data Extraction

Reg # 2382- RIO

Description: Product Registration

☐ Material(s) Sent to Data Extraction Contractors:

☒ New Stamped Label Dated 7-6-12

☐ Notification Dated _____

☐ New CSF(s) Dated _____

☐ Other: _____

☐ Decision #: _____


☐ Other Action/Comments: _____

Attach this coversheet to the top of the material or jacket. It must be well organized and clipped together, NOT STAPLED. Then give the material with this coversheet to staff in the Information Services Center (Room S-4900).

Reviewer: REGINA FOUSHEE-Smith

Phone: 605-0780 Division: RD

Date: _____

 <p align="center">ENVIRONMENTAL PROTECTION AGENCY</p> <p align="center">Office of Pesticide Programs Registration Division (7505P) 1200 Pennsylvania Ave., N.W. Washington, D.C. 20460</p>	EPA Registration No. <p align="center">2382-189</p>	Date of Issuance: <p align="center">July 6, 2012</p>
<p align="center">NOTICE OF PESTICIDE:</p> <p align="center"> <input checked="" type="checkbox"/> Registration <input type="checkbox"/> Reregistration </p> <p align="center">(under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended)</p>	Term of Issuance: <p align="center">Unconditional</p> Name of Pesticide Product: <p align="center">EFFIPRO® PLUS TOPICAL SOLUTION FOR DOGS</p>	
<p>Name and Address of Registrant (include ZIP Code):</p> <p>Virbac Animal Health, Inc. P.O. Box 162059 Fort Worth, TX 76161</p>		
<p>Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.</p>		
<p>On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.</p> <p>Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.</p> <p>This action is taken under the authority of section 3(c)(5) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended. Registration under this section does not eliminate the need for continual reassessment of pesticides. EPA may require submission of data at any time to maintain the registration of your product.</p>		
<p align="center">Terms of Registration</p> <ol style="list-style-type: none"> EPA has registered the product listed above provided that the following change is made to the label before you release the product for shipment: Revise the EPA Registration Number to read: "EPA Registration No 2382-189." The Net Contents must be displayed in accordance with the description identified in the Labeling Consistency Committee's clarification. This information may be located at the following Agency web site under miscellaneous http://www.epa.gov/opp00001/regulating/labels/label_review_faq.htm#miscellaneous. "Regarding listing net contents - Net weight or contents must be stated on a pesticide label in accordance with FIFRA (2)(q)(2)(C)(iii) and 40 CFR 156.10(a)(1)(iii). EPA interpretation of the statutory and regulatory requirements is that the label must state the total weight for the entire contents as sold and distributed. In 		
<p>Signature of Approving Official:</p> <p align="center">Refer to Page 3</p> Richard J. Gebken, Product Manager (10) Registration Division, Insecticide Branch	<p>Date:</p> <p align="center">July 6, 2012</p>	

addition, the label may indicate the net weight and quantity of individual units within the carton. For example, "Net Weight 6.25 lbs. (20 - 5oz. packets)." For additional information regarding the Net Weight/Contents statement, please reference Chapter 17 of the Label Review Manual at <http://www.epa.gov/oppead1/labeling/lrm/chap-17.htm>."

3. This registration is time-limited and expires two years from the date this product is first released for shipment. You must provide the Agency with a projected "release for shipment date", in writing within 30 days of the date of this Notice of Registration. The Agency will calculate the expiration date based on the projected "release for shipment date" until an actual release for shipment date is provided in writing.
4. Only one basic confidential statement of formula (CSF) will be on file for this product at any time (i.e., no alternate formulations or minor formulation amendments will be submitted and/or approved for this product, except to allow for alternate sources of any individual inert ingredient).
5. You must submit the following data within the timeframe described below:
Within sixteen (16) months of the date on this Notice of Registration, provide to the Agency acceptable data packages for Guideline Studies: OPPTS 830.6320 (Corrosion Characteristics) and OPPTS 830.6317 (Storage Stability).
6. You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product for the quarter that begins on August 1, 2012. The quarterly reports are due two months after the end of each quarter. Please flag any Confidential Business Information (CBI) as such. Enhanced incident reporting should be submitted to the Product Manager. Quarterly sales information should be submitted to the Registration Division, Immediate Office (attn: Kimberly Nesci).

The following is a list of information that must be included in the quarterly reports for each incident:

EPA Registration Number
Product name (brand name)
Lot#
Where purchased: internet, store, Veterinarian
Active Ingredient(s)
Weight range for product
Date on which incident occurred, (mm/dd/yyyy)
State in which the incident occurred, (standard 2 letter abbreviation)
Registrant case #
Species: dog, cat, other (specify)
Breed: (as reported by pet owner)
Age: months or years
Sex: M, F, or neutered
Weight: pounds
Primary Route of Exposure: dermal, oral, other animal, inhalation, other
Body System: neurological, dermatological, GI, respiratory, ocular, other Major signs noted
Time to Onset: (hours, days)
Treated by veterinarian: yes or no
First time product used: yes or no
Misuse: use on incorrect species, overdose, too frequent dosing, other (describe)
Any known precondition
EPA Severity Code: death, major, moderate, minor
Outcome: died, recovered, still treated, unknown

7. Along with the enhanced incident reporting, you must submit an analysis of all incidents seen, to include the following details:
 - a. All minor dermal and ocular irritation reports.
 - b. Summary table for dogs showing number of incidents of each severity code for each route of exposure. Each incident should only be reported once. If one incident has several routes of exposure, the order should be ocular > oral > dermal. In other words, an incident with both oral and dermal exposure would be reported as oral exposure, and an incident with both ocular and oral exposure would be reported as ocular exposure.
 - c. A similar summary table for cats (misuse or secondary exposure) showing number of incidents of each severity code for each route of exposure.
 - d. Summary table for dogs and table for cats showing number of incidents that are believed due to

secondary exposure (e.g., multi-pet households).

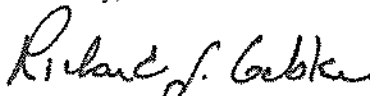
- e. A summary table for dogs showing number of incidents for each severity code for these age ranges: <3 months, 3-6 months, 6-9 months, 9-12 months, 1 yr, 2 yr, 3 yr, 4 yr, 5 yr, 6 yr, 7 yr, 8 yr, 9 yr, 10 yr, 11 yr, 12 yr, 13 yr, 14 yr, 15 yr, >15 yr.
 - f. A summary table showing the number of dog incidents for each severity code for each pet weight range on the product label.
 - g. A summary table for dog weight showing number of incidents for each product weight range. This table should show number of incidents in dogs weighing less than that product weight range, number of incidents in dogs in lower half of weight range, number of incidents in dogs in upper half of weight range, and dogs weighing more than the product weight range.
 - h. Table showing number of incidents for each dog breed.
 - i. Table showing number of incidents in dogs for each clinical sign.
 - j. Table showing number of incidents in dogs for each organ system.
 - k. Report aggregate incidents, but do not combine moderate and minor incidents.
8. If EPA determines that future mitigation measures are necessary for all pet spot-on products, the Agency will inform all registrants concerned. If mitigation measures are necessary, EPA may take regulatory action.
 9. Virbac Inc. should adequately address all of the mitigation actions identified in the Agency's *Generic Pet Spot-On Mitigation Plan* available at the following internet site: <http://www.epa.gov/pesticides/health/spot-on-meetings.html>.

You must submit and/or cite all data required for registration of your product under FIFRA Section 3(c)(5) when the Agency requires all registrants of similar products to submit such data, and submit acceptable responses required for registration review of your product under FIFRA.

Two copies of the finished labeling must be submitted prior to releasing the product for shipment. If you fail to comply with all of the **Terms of Registration** stated above, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e) and/or automatically expire. Your release for shipment of the product constitutes your acceptance of these conditions.

A copy of your label stamped "Accepted with Comments" is enclosed for your records. If you have any questions concerning this action, please contact me Richard J. Gebken at (703) 305-6701 or gebken.richard@epa.gov.

Sincerely,



Richard Gebken
Product Manager 10
Insecticide Branch
Registration Division (7505C)

Enclosure

{Master Label}
Virbac's Master Label

Date December 14, 2011 Version US-8 EPA Reg. No. 2382-XXX
Fipronil + Pyriproxyfen Topical Solution for Dogs

Virbac
EFFIPRO[®] PLUS TOPICAL SOLUTION FOR
DOGS

FOR USE ONLY ON DOGS AND PUPPIES 8 WEEKS OLD OR OLDER (WEIGHING)(UP TO 22.9 LBS,
[WEIGHING] 23 TO 44.9 LBS, [WEIGHING] 45 TO 88.9 LBS, [WEIGHING] 89 TO 132 lbs).

ACTIVE INGREDIENTS:

Fipronil..... 9.7%
Pyriproxyfen..... 2.9%

OTHER INGREDIENTS: 87.4%

TOTAL: 100.0%

KEEP OUT OF REACH OF CHILDREN
CAUTION
READ ENTIRE LABEL BEFORE EACH USE

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

ACCEPTED
with COMMENTS
In EPA Letter Dated

July 6, 2012
Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, for the pesticide
registered under EPA Reg. No.
2382-189

HAZARDS TO HUMANS

Harmful if swallowed or absorbed through the skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

HAZARDS TO DOMESTIC ANIMALS

For external use only. Do not use on puppies under 8 weeks of age. Sensitivities may occur after using ANY pesticide product for pets. If signs of sensitivity occur bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately. Possible temporary irritation may occur at the site where EFFIPRO[®] PLUS Topical Solution for Dogs was applied. Contact a veterinarian immediately if signs become persistent or become more severe during the first few days following application. If an unusual reaction is observed following initial application, a veterinarian should be consulted before repeating application. Certain medications can interact with pesticides.

	FIRST AID
IF SWALLOWED:	<ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by a poison control center or doctor. • Do not give anything by mouth to an unconscious person.
IF IN EYES:	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
IF ON SKIN OR CLOTHING:	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.

Have product container or label with you when calling a poison control center or doctor, or going for treatment.
You may also contact the Hotline number 1-800-338-3659 for human and veterinary health concerns, emergency medical treatment information or pesticide incidents.

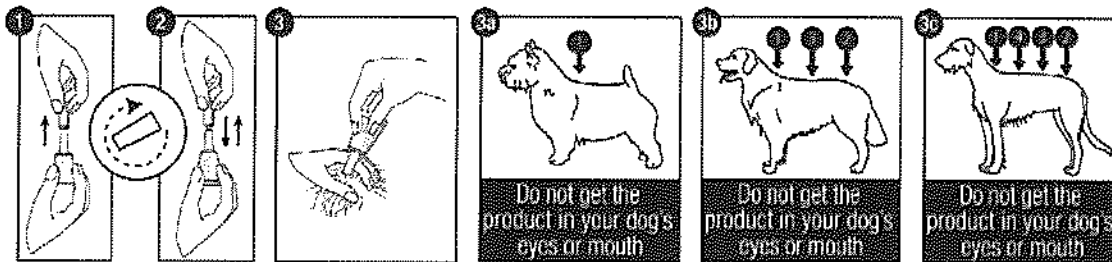
DIRECTIONS FOR USE

It is a violation of Federal law to use this product in any manner inconsistent with its labeling. Do not allow children to apply product. TO PREVENT HARM TO YOU AND YOUR DOG, READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON DOGS ONLY. DO NOT USE ON CATS, KITTENS, OR RABBITS. DO NOT USE ON OTHER ANIMALS.

For killing fleas, flea eggs, flea larvae, all stages of Brown dog ticks, American dog ticks, Lone Star ticks, and Deer ticks (that may [which may] transmit [carry] Lyme disease), mosquitoes and chewing lice: apply to DOGS or PUPPIES (8 weeks old or older) as follows:

APPLICATION DIRECTIONS

1. Remove one applicator from packaging.
Hold applicator upright and remove cap.
2. Invert cap and place other end back onto applicator tip.
Push cap down to break seal.
Remove cap prior to treatment application.
3. Part dog's hair between shoulder blades until skin is visible.
Place applicator tip directly against exposed skin.
- 3a. For small dogs (12 weeks old or older) and weighing up to 22.9 lbs- Deposit entire contents by squeezing the entire applicator contents onto dog's skin, at a single site, between the shoulder blades as shown in diagram 3a.
- 3b. For medium dogs 23-44.9 lbs or large dogs 45-88.9 lbs- Apply the product evenly to three spots on the dog's back, starting between the shoulder blades and continuing on to the second and third spots as shown in diagram 3b, squeezing the applicator until empty.
- 3c. For extra large dogs 89-132 lbs- Apply the product evenly to four spots on the dog's back, starting between the shoulder blades and continuing on to the second, third and fourth spots as shown in diagram 3c, squeezing the applicator until empty. Ensure that EFFIPRO® PLUS Topical Solution for Dogs is not applied superficially on dog's hair.



FREQUENCY OF APPLICATION

Research has shown that flea, tick and chewing lice infestations can be controlled with monthly applications of EFFIPRO® PLUS Topical Solution for Dogs.

Fleas: EFFIPRO® PLUS Topical Solution for Dogs can kill adult fleas for up to three months. Apply monthly if your dog has fleas that may cause Flea Allergy Dermatitis (FAD), or if reinfestation is likely. EFFIPRO® PLUS Topical Solution for Dogs can control flea eggs for up to three months (90 days).

Ticks: EFFIPRO® PLUS Topical Solution for Dogs can kill ticks for a month or longer. Apply monthly where tick control is consistently needed.

Chewing Lice: EFFIPRO® PLUS Topical Solution for Dogs can kill chewing lice for a month or longer. Apply monthly where chewing lice control is consistently needed.

Mosquitoes: When applied monthly, EFFIPRO® PLUS Topical Solution for Dogs can kill mosquitoes within 24 hours (for up to 7 days) and within 48 hours (for up to 28 days).

Notes: Wait at least 30 days before re-application of EFFIPRO® PLUS Topical Solution for Dogs. Avoid contact with treated area until dry.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

STORAGE: Store unused product in original container only, out of reach of children and animals.

PESTICIDE/CONTAINER DISPOSAL: If empty: Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available. If partially filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

LIMITED WARRANTY AND DISCLAIMER

To the extent consistent with applicable law, buyer assumes all risks of use, storage, or handling of this product not in accordance with directions. Buyer and user assume all risks of use and handling of this material when such use and handling are contrary to label instructions. To the extent consistent with applicable law, any damage arising from a breach of this

warranty shall be limited to direct damages and shall not include consequential commercial damages such as loss of profit or values.

How supplied: For easy and convenient application, EFFIPRO® PLUS Topical Solution for Dogs is available in sizes for small dogs and puppies 8 weeks old or older and up to 22.9 lbs (0.023 fl oz)/(0.67 mL), medium dogs 23-44.9 lbs (0.045 fl oz)/(1.34 mL), large dogs 45-88.9 lbs (0.091 fl oz)/(2.68 mL), and extra large dogs 89-132 lbs (0.136 fl oz)/(4.02 mL).

Net Contents:

1, 3, 6 or 36 single-dose applicator(s) per package. Each applicator contains 0.023 fl oz (0.67 mL), 0.045 fl oz (1.34 mL), 0.091 fl oz (2.68 mL), or 0.136 fl oz (4.02 mL) (of solution).

(Detachable) calendar (monthly application) reminder stickers (with illustration of dog or puppy)

EPA Reg. No. 2382-xxx

EPA Est. No. 2382-xxxx

Virbac AH, INC.
PO BOX 162059
FORT WORTH, TX 76161
1-800-338-3659

Made in France
EFFIPRO® is a registered trademark of Virbac S.A. in the United States
Questions or comments?
Call: 1-800-338-3659

{Text for Front Panel, Back Panel and Side Panel}

See package insert(s) for directions for use and frequency of application
Open resealable label for directions for use
Open resealable label for directions for use and storage and disposal
See back panel for additional precautionary statements
See package insert(s) for frequency of application
See enclosed insert(s) for directions for use and storage and disposal
See enclosed insert(s) for directions for use

Photograph of dog or puppy

Lift here to open (LIFT HERE TO OPEN)
For Use on Dogs only
Use only on dogs

{Text for Foil of Blister package}

Virbac
EFFIPRO® PLUS Topical Solution for Dogs
Only for use (on dogs up to 22.9 lbs, on dogs 23-44.9 lbs, on dogs 45-88.9 lbs, on dogs 89-132 lbs) / (0.023 fl oz [0.67 mL], 0.045 fl oz [1.34 mL], 0.091 fl oz [2.68 mL], 0.136 fl oz [4.02 mL]).
Contains fipronil (9.7%) and pyriproxyfen (2.9%)
KEEP OUT OF REACH OF CHILDREN
CAUTION
See full label for additional directions
EPA Reg. No. 2382-xxx

{Text for Applicator Tube}

Virbac
EFFIPRO® PLUS
Topical Solution for Dogs
Only for use on dogs
up to 22.9 lbs (23-44.9 lbs, 45-88.9 lbs, 89-132 lbs)
0.023 fl oz [0.67 mL] (0.045 fl oz [1.34 mL], 0.091 fl oz [2.68 mL], 0.136 fl oz [4.02 mL])
Contains fipronil (9.7%) and pyriproxyfen (2.9%)
KEEP OUT OF REACH OF CHILDREN
CAUTION
See full label for additional directions
EPA Reg. No. 2382-xxx

MARKETING CLAIMS

[Multiple infestations]

- For convenient, quick-acting, long-lasting, effective control of fleas, ticks, mosquitoes and chewing lice.
- For convenient, quick-acting, long-lasting, effective control of fleas, flea eggs, flea larvae, ticks, mosquitoes and chewing lice.
- EFFIPRO® PLUS Topical Solution for Dogs contains the active ingredient fipronil, which controls infestations caused by fleas, ticks, mosquitoes and chewing lice (on dogs) (DOGS or PUPPIES) (8 weeks old or older) (weighing up to 22.9 lbs, weighing 23 to 44.9 lbs, weighing 45 to 88.9 lbs, weighing 89 to 132 lbs).
- EFFIPRO® PLUS Topical Solution for Dogs contains the active ingredient pyriproxyfen, which controls reinfestations caused by fleas eggs and flea larvae (on dogs) (DOGS or PUPPIES) (8 weeks old or older) (weighing up to 22.9 lbs, weighing 23 to 44.9 lbs, weighing 45 to 88.9 lbs, weighing 89 to 132 lbs).
- For easy and convenient application, EFFIPRO® PLUS Topical Solution for Dogs is available in sizes for small dogs and puppies 8 weeks old or older and up to 22.9 lbs (0.023 fl oz) (0.67 mL), medium dogs 23-44.9 lbs (0.045 fl oz) (1.34 mL), large dogs 45-88.9 lbs (0.091 fl oz) (2.68 mL), and extra large dogs 89-132 lbs (0.136 fl oz) (4.02 mL).
- For killing fleas, (flea eggs, flea larvae,) all stages of Brown dog ticks, American dog ticks, Lone Star ticks, and Deer ticks (that [which] may transmit [carry] Lyme disease), mosquitoes and chewing lice; apply to DOGS or PUPPIES (8 weeks old or older) as follows: (followed by application directions).
- Persistent flea and tick efficacy for up to one month (4 weeks)
- Prevents flea and tick (re-)infestation for up to one month (4 weeks)
- Kills fleas and ticks for up to one month (4 weeks)
- Apply monthly for control and prevention of fleas and ticks
- Kills fleas and ticks that may transmit Lyme disease, Rocky Mountain Spotted Fever, babesiosis, ehrlichiosis, bartonellosis (and hepatozoonosis).
- Kills fleas, (flea eggs, flea larvae,) ticks, mosquitoes and chewing lice
- Kills fleas, (flea eggs, flea larvae,) ticks, mosquitoes and lice
- Effective monthly control of fleas and ticks
- Effective monthly application for fleas and ticks
- Effective monthly application for dogs against fleas and ticks
- Single application kills fleas and ticks
- Single application lasts 4 weeks (one month)
- Research has shown that flea, tick and chewing lice infestations can be completely controlled with monthly applications of EFFIPRO® PLUS Topical Solution for Dogs.
- Fleas: EFFIPRO® PLUS Topical Solution for Dogs can kill adult fleas, flea eggs and flea larvae for up to three months. Apply monthly if your dog has fleas that may cause Flea Allergy Dermatitis (FAD), or if reinfestation is likely.
- Ticks: EFFIPRO® PLUS Topical Solution for Dogs can kill ticks for a month or longer. Apply monthly where tick control is consistently needed.
- Chewing Lice: EFFIPRO® PLUS Topical Solution for Dogs can kill chewing lice for a month or longer. Apply monthly where chewing lice control is consistently needed.
- Mosquitoes: When applied monthly, EFFIPRO® PLUS Topical Solution for Dogs can kill mosquitoes within 24 hours (for up to 7 days) and within 48 hours (for up to 28 days).

[Fleas]

- Kills newly emerged adult fleas prior to egg laying
- Kills fleas, flea eggs and flea larvae
- Sterilizes and kills (adult) fleas
- Prevents all flea stages (adult fleas, flea eggs, flea pupae and flea larvae)
- Prevents development of all flea stages (flea eggs, flea pupae and flea larvae) for up to (3 months) (90 days)
- With pyriproxyfen (IGR)* to break flea life cycle
- * insect growth regulator
- Dual Action(!): fipronil and pyriproxyfen (IGR) effectively breaks the flea life cycle
- Kills fleas that may transmit bartonellosis
- Kills fleas that may transmit (bartonellosis), (tularemia) (and) (tapeworm)
- Kills fleas that may transmit (bartonellosis), (tularemia) (and) (tapeworm infestations).
- Kills fleas that may cause Flea Allergy Dermatitis (FAD) or flea-bite anemia
- Effective monthly application against fleas
- Effective monthly control of fleas
- Kills adult fleas for up to one month (4 weeks)
- Kills fleas
- Easy to apply, control of (for) fleas that lasts 1 month (4 weeks)
- Easy to apply, flea control that lasts up to 1 (one) month (4 weeks)
- EFFIPRO® PLUS Topical Solution for Dogs kills fleas on your dog
- Kills adult fleas which may cause Flea Allergy Dermatitis (FAD)
- Kills fleas which (that) may cause flea-bite anemia
- Fleas do not have to bite to die
- EFFIPRO® PLUS Topical Solution for Dogs rapidly kills fleas that may cause FAD (Flea Allergy Dermatitis)
- The successive feeding activity of fleas on dogs may elicit a hypersensitivity skin disorder known as Flea Allergy Dermatitis (FAD)
- Prevents flea eggs from hatching or developing into larvae or adult stages (for up to 90 days (3 months))

[Ticks]

- Kills all stages of Brown dog ticks, American dog ticks, Lone Star ticks, and Deer ticks (including those that may transmit Lyme disease, Rocky Mountain Spotted Fever, babesiosis, ehrlichiosis and anaplasmosis)
- Kills ticks including Deer ticks (that may transmit Lyme disease), American dog ticks (that may transmit Rocky Mountain Spotted Fever), Brown dog ticks (that may transmit ehrlichiosis), and Lone Star ticks (that may transmit hepatozoonosis) for up to one month (4 weeks).
- Kills ticks including Deer ticks (that may transmit Lyme disease), American dog ticks (that may transmit Rocky Mountain Spotted Fever), and Brown dog ticks (that may transmit ehrlichiosis) for up to one month (4 weeks).
- Kills Brown dog ticks (*Rhipicephalus* spp), American dog ticks (*Dermacentor variabilis*), Deer ticks (*Ixodes* spp) and Lone Star ticks (*Amblyomma americanum*) for up to one month (4 weeks).
- Kills Lone Star ticks (*Amblyomma americanum*) for 4 weeks (for up to one month).
- Effective monthly application against ticks

[Mosquitoes]

- Kills mosquitoes
- Kills mosquitoes for up to 28 days

[All others]

- EFFIPRO® PLUS Topical Solution for Dogs aids in (the) control of sarcoptic mange mite infestations.
- Aids in (the) control of sarcoptic mange mite infestations
- Elimination of sarcoptic mange mites may require multiple monthly applications.
- Chewing lice infestations are rapidly eliminated
- May be used on puppies from 8 weeks of age
- Only for dogs and puppies 8 weeks old or older (weighing up to 22.9 lbs, 23 to 44.9 lbs, weighing 45 to 88.9 lbs, weighing 89 to 132 lbs)
- Easy, spot-on (topical) application
- Convenient topical application for dogs
- Easy to apply spot-on (topical) application
- Quick drying, non-greasy
- Convenient, easy to apply
- Easy and convenient application (applications)
- Convenient to use (easy to apply)
- Once monthly application
- Single application lasts up to 4 weeks (1 month) (one month)
- 1 (3, 6 or 36) applicator(s) (tube(s)) 0.023 fl oz (0.67 mL)
- 1 (3, 6 or 36) applicator(s) (tube(s)) 0.045 fl oz (1.34 mL)
- 1 (3, 6 or 36) applicator(s) (tube(s)) 0.091 fl oz (2.68 mL)
- 1 (3, 6 or 36) applicator(s) (tube(s)) 0.136 fl oz (4.02 mL)
- 1 (3, 6, 36) month(ly) dose(s) (applications)
- 1 (3, 6 or 36) applicator(s) (tube(s)) (each) containing 0.023 fl oz (0.67 mL)
- 1 (3, 6 or 36) applicator(s) (tube(s)) (each) containing 0.045 fl oz (1.34 mL)
- 1 (3, 6 or 36) applicator(s) (tube(s)) (each) containing 0.091 fl oz (2.68 mL)
- 1 (3, 6 or 36) applicator(s) (tube(s)) (each) containing 0.136 fl oz (4.02 mL)
- 1 applicator (tube) 1 month(ly) dose
- 3 applicators (tubes) 3 monthly doses (applications)
- 6 applicators (tubes) 6 monthly doses (applications)
- 36 applicators (tubes) 36 monthly doses (applications)
- 1 (3, 6, 36) applicator(s) containing 0.023 fl oz [0.67 mL], (0.045 fl oz [1.34 mL], 0.091 fl oz [2.68 mL], 0.136 fl oz [4.02 mL])
- Available from veterinarians
- Remains effective after exposure to sunlight
- Remains effective after bathing and swimming
- Remains effective even after bathing, water immersion or exposure to rain or sunlight
- Remains effective even after bathing
- Remains effective after exposure to rain and sunlight
- Still works after bathing, swimming or exposure to sunlight
- Still works after exposure to sunlight
- Maintains residual efficacy after bathing and swimming
- EFFIPRO® PLUS Topical Solution for Dogs is effective after bathing, shampooing, water immersion, or sunlight exposure.
- Waterproof (remains effective after bathing and swimming)

{Master Label}
Virbac's Master Label

Date December 14, 2011 Version US-8 EPA Reg. No. 2382-XXX
 Fipronil + Pyriproxyfen Topical Solution for Dogs

Virbac
EFFIPRO[®] PLUS TOPICAL SOLUTION FOR DOGS

FOR USE ONLY ON DOGS AND PUPPIES 8 WEEKS OLD OR OLDER (WEIGHING)(UP TO 22.9 LBS, [WEIGHING] 23 TO 44.9 LBS, [WEIGHING] 45 TO 88.9 LBS, [WEIGHING] 89 TO 132 lbs).

ACTIVE INGREDIENTS:
 Fipronil9.7%
 Pyriproxyfen2.9%
 OTHER INGREDIENTS: 87.4%
 TOTAL: 100.0%

KEEP OUT OF REACH OF CHILDREN
CAUTION
 READ ENTIRE LABEL BEFORE EACH USE

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

HAZARDS TO HUMANS

Harmful if swallowed. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

HAZARDS TO DOMESTIC ANIMALS

For external use only. Do not use on puppies under 8 weeks of age. Individual sensitivities, while rare, may occur after using ANY pesticide product. Possible temporary irritation may occur at the site where EFFIPRO[®] PLUS Topical Solution for Dogs was applied. Contact a veterinarian immediately if signs become persistent or become more severe during the first few days following application. If an unusual reaction is observed following initial application, a veterinarian should be consulted before repeating application. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated or aged dogs.

FIRST AID	
IF SWALLOWED:	<ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by a poison control center or doctor. • Do not give anything by mouth to an unconscious person.
IF IN EYES:	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
IF ON SKIN OR CLOTHING:	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
Have product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact the Hotline number 1-800-338-3659 for human and veterinary health concerns, emergency medical treatment information or pesticide incidents.	

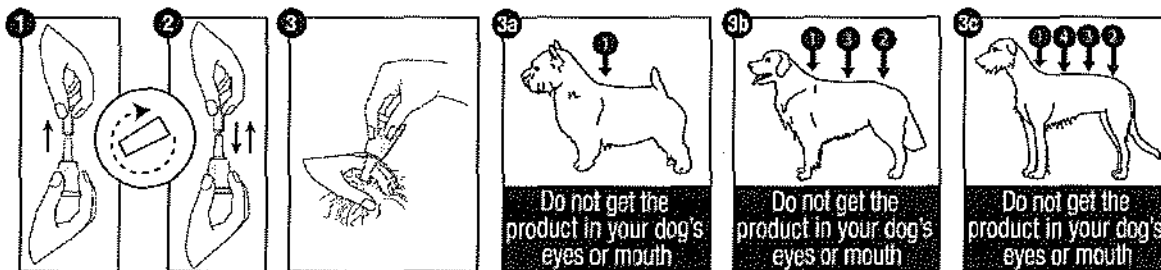
DIRECTIONS FOR USE

It is a violation of Federal law to use this product in any manner inconsistent with its labeling. Do not allow children to apply product. TO PREVENT HARM TO YOU AND YOUR DOG, READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON DOGS ONLY. DO NOT USE ON RABBITS. DO NOT USE ON OTHER ANIMALS.

For killing fleas, flea eggs, flea larvae, all stages of Brown dog ticks, American dog ticks, Lone Star ticks, and Deer ticks (that may [which may] transmit [carry] Lyme disease), mosquitoes and chewing lice; apply to DOGS or PUPPIES (8 weeks old or older) as follows:

APPLICATION DIRECTIONS

1. Remove one applicator from packaging. Hold applicator upright and remove cap.
2. Invert cap and place other end back onto applicator lip. Push cap down to break seal. Remove cap prior to treatment application.
3. Part dog's hair between shoulder blades until skin is visible. Place applicator tip directly against exposed skin.
- 3a. For small dogs (12 weeks old or older) and weighing up to 22.9 lbs- Deposit entire contents by squeezing the entire applicator contents onto dog's skin, at a single site, between the shoulder blades as shown in diagram 3a.
- 3b. For medium dogs 23-44.9 lbs or large dogs 45-88.9 lbs- Apply the product evenly to three spots on the dog's back, starting between the shoulder blades and continuing on to the second and third spots as shown in diagram 3b, squeezing the applicator until empty.
- 3c. For extra large dogs 89-132 lbs- Apply the product evenly to four spots on the dog's back, starting between the shoulder blades and continuing on to the second, third and fourth spots as shown in diagram 3c, squeezing the applicator until empty. Ensure that EFFIPRO® PLUS Topical Solution for Dogs is not applied superficially on dog's hair.



FREQUENCY OF APPLICATION

Research has shown that flea, tick and chewing lice infestations can be controlled with monthly applications of EFFIPRO® PLUS Topical Solution for Dogs.

Fleas: EFFIPRO® PLUS Topical Solution for Dogs can kill adult fleas for up to three months. Apply monthly if your dog has fleas that may cause Flea Allergy Dermatitis (FAD), or if reinfestation is likely. EFFIPRO® PLUS Topical Solution for Dogs can control flea eggs for up to three months (90 days).

Ticks: EFFIPRO® PLUS Topical Solution for Dogs can kill ticks for a month or longer. Apply monthly where tick control is consistently needed.

Chewing Lice: EFFIPRO® PLUS Topical Solution for Dogs can kill chewing lice for a month or longer. Apply monthly where chewing lice control is consistently needed.

Mosquitoes: When applied monthly, EFFIPRO® PLUS Topical Solution for Dogs can kill mosquitoes within 24 hours (for up to 7 days) and within 48 hours (for up to 28 days).

Notes: Wait at least 30 days before re-application of EFFIPRO® PLUS Topical Solution for Dogs. Avoid contact with treated area until dry.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

STORAGE: Store unused product in original container only, out of reach of children and animals.

PESTICIDE/CONTAINER DISPOSAL: If empty: Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available. If partially filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

LIMITED WARRANTY AND DISCLAIMER

To the extent consistent with applicable law, buyer assumes all risks of use, storage, or handling of this product not in accordance with directions. Buyer and user assume all risks of use and handling of this material when such use and handling are contrary to label instructions. To the extent consistent with applicable law, any damage arising from a breach of this warranty shall be limited to direct damages and shall not include consequential commercial damages such as loss of profit or values.

How supplied: For easy and convenient application, EFFIPRO® PLUS Topical Solution for Dogs is available in sizes for small dogs and puppies 8 weeks old or older and up to 22.9 lbs (0.023 fl oz)/(0.67 mL), medium dogs 23-44.9 lbs (0.045 fl oz)/(1.34 mL), large dogs 45-88.9 lbs (0.091 fl oz)/(2.68 mL), and extra large dogs 89-132 lbs (0.136 fl oz)/(4.02 mL).

Net Contents:

1, 3, 6 or 36 single-dose applicator(s) per package. Each applicator contains 0.023 fl oz (0.67 mL), 0.045 fl oz (1.34 mL), 0.091 fl oz (2.68 mL), or 0.136 fl oz (4.02 mL) (of solution).

(Detachable) calendar (monthly application) reminder stickers (with illustration of dog or puppy)

EPA Reg. No. 2382-xxx

EPA Est. No. 2382-xxxx

VIRBAC AH, INC.
PO BOX 162059
FORT WORTH, TX 76161
1-800-338-3659

Made in France

EFFIPRO® is a registered trademark of Virbac S.A. in the United States

Questions or comments?

Call: 1-800-338-3659

{Text for Front Panel, Back Panel and Side Panel}

See package insert(s) for directions for use and frequency of application

Open resealable label for directions for use

Open resealable label for directions for use and storage and disposal

See back panel for additional precautionary statements

See package insert(s) for frequency of application

See enclosed insert(s) for directions for use and storage and disposal

See enclosed insert(s) for directions for use

Photograph of dog or puppy

Lift here to open (LIFT HERE TO OPEN)

For Use on Dogs only

Use only on dogs

{Text for Foil of Blister package}

Virbac

EFFIPRO® PLUS Topical Solution for Dogs

Only for use (on dogs up to 22.9 lbs, on dogs 23-44.9 lbs, on dogs 45-88.9 lbs, on dogs 89-132 lbs) / (0.023 fl oz [0.67 mL], 0.045 fl oz [1.34 mL], 0.091 fl oz [2.68 mL], 0.136 fl oz [4.02 mL]).

Contains flupronil (9.7%) and pyriproxyfen (2.9%)

KEEP OUT OF REACH OF CHILDREN

CAUTION

See full label for additional directions

EPA Reg. No. 2382-xxx

{Text for Applicator Tube}

Virbac

EFFIPRO® PLUS

Topical Solution for Dogs

Only for use on dogs

up to 22.9 lbs (23-44.9 lbs, 45-88.9 lbs, 89-132 lbs)
0.023 fl oz [0.67 mL] (0.045 fl oz [1.34 mL], 0.091 fl oz [2.68 mL], 0.136 fl oz [4.02 mL])

Contains flupronil (9.7%) and pyriproxyfen (2.9%)

KEEP OUT OF REACH

OF CHILDREN

CAUTION

See full label for additional directions

EPA Reg. No. 2382-xxx

MARKETING CLAIMS

(Multiple Infestations)

- For convenient, quick-acting, long-lasting, effective control of fleas, ticks, mosquitoes and chewing lice.
- For convenient, quick-acting, long-lasting, effective control of fleas, flea eggs, flea larvae, ticks, mosquitoes and chewing lice.
- EFFIPRO[®] PLUS Topical Solution for Dogs contains the active ingredient fipronil, which controls infestations caused by fleas, ticks, mosquitoes and chewing lice (on dogs) (DOGS or PUPPIES) (8 weeks old or older) (weighing up to 22.9 lbs, weighing 23 to 44.9 lbs, weighing 45 to 88.9 lbs, weighing 89 to 132 lbs).
- EFFIPRO[®] PLUS Topical Solution for Dogs contains the active ingredient pyriproxyfen, which controls reinfestations caused by fleas eggs and flea larvae (on dogs) (DOGS or PUPPIES) (8 weeks old or older) (weighing up to 22.9 lbs, weighing 23 to 44.9 lbs, weighing 45 to 88.9 lbs, weighing 89 to 132 lbs).
- For easy and convenient application, EFFIPRO[®] PLUS Topical Solution for Dogs is available in sizes for small dogs and puppies 8 weeks old or older and up to 22.9 lbs (0.023 fl oz) (0.67 mL), medium dogs 23-44.9 lbs (0.045 fl oz) (1.34 mL), large dogs 45-88.9 lbs (0.091 fl oz) (2.68 mL), and extra large dogs 89-132 lbs (0.136 fl oz) (4.02 mL).
- For killing fleas, (flea eggs, flea larvae,) all stages of Brown dog ticks, American dog ticks, Lone Star ticks, and Deer ticks (that which may transmit (carry) Lyme disease), mosquitoes and chewing lice; apply to DOGS or PUPPIES (8 weeks old or older) as follows: (followed by application directions).
- Persistent flea and tick efficacy for up to one month (4 weeks)
- Prevents flea and tick (re-)infestation for up to one month (4 weeks)
- Kills fleas and ticks for up to one month (4 weeks)
- Apply monthly for control and prevention of fleas and ticks
- Kills fleas and ticks that may transmit Lyme disease, Rocky Mountain Spotted Fever, babesiosis, ehrlichiosis, bartonellosis (and hepatozoonosis).
- Kills fleas, (flea eggs, flea larvae,) ticks, mosquitoes and chewing lice
- Kills fleas, (flea eggs, flea larvae,) ticks, mosquitoes and lice
- Effective monthly control of fleas and ticks
- Effective monthly application for fleas and ticks
- Effective monthly application for dogs against fleas and ticks
- Single application kills fleas and ticks
- Single application lasts 4 weeks (one month)
- Research has shown that flea, tick and chewing lice infestations can be completely controlled with monthly applications of EFFIPRO[®] PLUS Topical Solution for Dogs.
Fleas: EFFIPRO[®] PLUS Topical Solution for Dogs can kill adult fleas, flea eggs and flea larvae for up to three months. Apply monthly if your dog has fleas that may cause Flea Allergy Dermatitis (FAD), or if reinfestation is likely.
Ticks: EFFIPRO[®] PLUS Topical Solution for Dogs can kill ticks for a month or longer. Apply monthly where tick control is consistently needed.
Chewing Lice: EFFIPRO[®] PLUS Topical Solution for Dogs can kill chewing lice for a month or longer. Apply monthly where chewing lice control is consistently needed.
Mosquitoes: When applied monthly, EFFIPRO[®] PLUS Topical Solution for Dogs can kill mosquitoes within 24 hours (for up to 7 days) and within 48 hours (for up to 28 days).

(Fleas)

- Kills newly emerged adult fleas prior to egg laying
- Kills fleas, flea eggs and flea larvae
- Sterilizes and kills (adult) fleas
- Prevents all flea stages (adult fleas, flea eggs, flea pupae and flea larvae)
- Prevents development of all flea stages (flea eggs, flea pupae and flea larvae) for up to (3 months) (90 days)
- With pyriproxyfen (IGR) to break flea life cycle
- Dual Action(!): fipronil and pyriproxyfen (IGR) effectively breaks the flea life cycle
- Kills fleas that may transmit bartonellosis
- Kills fleas that may transmit bartonellosis, tularemia and tapeworm
- Kills fleas that may transmit diseases, including bartonellosis, tularemia (and tapeworm infestations).
- Kills fleas that may cause Flea Allergy Dermatitis (FAD) or flea-bite anemia
- Effective monthly application against fleas
- Effective monthly control of fleas
- Kills adult fleas for up to one month (4 weeks)
- Kills fleas
- Easy to apply, control of (for) fleas that lasts 1 month (4 weeks)
- Easy to apply, flea control that lasts up to 1 (one) month (4 weeks)
- EFFIPRO[®] PLUS Topical Solution for Dogs kills fleas on your dog
- Kills adult fleas which may cause Flea Allergy Dermatitis (FAD)
- Kills fleas which (that) may cause flea-bite anemia
- Fleas do not have to bite to die
- EFFIPRO[®] PLUS Topical Solution for Dogs rapidly kills fleas that may cause FAD (Flea Allergy Dermatitis)
- The successive feeding activity of fleas on dogs may elicit a hypersensitivity skin disorder known as Flea Allergy Dermatitis (FAD)
- Prevents flea eggs from hatching or developing into larvae or adult stages (for up to 90 days (3 months))

(Ticks)

- Kills all stages of Brown dog ticks, American dog ticks, Lone Star ticks, and Deer ticks (including those that may transmit Lyme disease, Rocky Mountain Spotted Fever, babesiosis, ehrlichiosis and anaplasmosis)
- Kills ticks including Deer ticks (that may transmit Lyme disease), American dog ticks (that may transmit Rocky Mountain Spotted Fever), Brown dog ticks (that may transmit ehrlichiosis), and Lone Star ticks (that may transmit hepatzoonosis) for up to one month (4 weeks).
- Kills ticks including Deer ticks (that may transmit Lyme disease), American dog ticks (that may transmit Rocky Mountain Spotted Fever), and Brown dog ticks (that may transmit ehrlichiosis) for up to one month (4 weeks).
- Kills Brown dog ticks (*Rhipicephalus* spp), American dog ticks (*Dermacentor variabilis*), Deer ticks (*Ixodes* spp) and Lone Star ticks (*Amblyomma americanum*) for up to one month (4 weeks).
- Kills *Amblyomma americanum* (Lone Star ticks) for 4 weeks (for up to one month).
- Effective monthly application against ticks

[Mosquitoes]

- Kills mosquitoes
- Kills mosquitoes for up to 28 days

[All others]

- EFFIPRO® PLUS Topical Solution for Dogs aids in (the) control of sarcoptic mange mite infestations.
- Aids in (the) control of sarcoptic mange mite infestations
- Elimination of mites may require multiple monthly applications.
- Chewing lice infestations are rapidly eliminated
- May be used on puppies from 8 weeks of age
- Only for dogs and puppies 8 weeks old or older (weighing up to 22.9 lbs, 23 to 44.9 lbs, weighing 45 to 88.9 lbs, weighing 89 to 132 lbs)
- Easy, spot-on (topical) application
- Convenient topical application for dogs
- Easy to apply spot-on (topical) application
- Quick drying, non-greasy
- Convenient, easy to apply
- Easy and convenient application (applications)
- Convenient to use (easy to apply)
- Once monthly application
- Single application lasts up to 4 weeks (1 month) (one month)
- 1 (3, 6 or 36) applicator(s) [tube(s)] 0.023 fl oz (0.67 mL)
- 1 (3, 6 or 36) applicator(s) [tube(s)] 0.045 fl oz (1.34 mL)
- 1 (3, 6 or 36) applicator(s) [tube(s)] 0.091 fl oz (2.68 mL)
- 1 (3, 6 or 36) applicator(s) [tube(s)] 0.136 fl oz (4.02 mL)
- 1 (3, 6, 36) month(ly) dose(s) (applications)
- 1 (3, 6 or 36) applicator(s) (tube(s)) (each) containing 0.023 fl oz (0.67 mL)
- 1 (3, 6 or 36) applicator(s) (tube(s)) (each) containing 0.045 fl oz (1.34 mL)
- 1 (3, 6 or 36) applicator(s) (tube(s)) (each) containing 0.091 fl oz (2.68 mL)
- 1 (3, 6 or 36) applicator(s) (tube(s)) (each) containing 0.136 fl oz (4.02 mL)
- 1 applicator (tube) 1 month(ly) dose
- 3 applicators (tubes) 3 monthly doses (applications)
- 6 applicators (tubes) 6 monthly doses (applications)
- 36 applicators (tubes) 36 monthly doses (applications)
- 1 (3, 6, 36) applicator(s) containing 0.023 fl oz (0.67 mL), (0.045 fl oz [1.34 mL], 0.091 fl oz [2.68 mL], 0.136 fl oz [4.02 mL])
- Available from licensed veterinarians
- Remains effective after exposure to sunlight
- Remains effective after bathing and swimming
- Remains effective even after bathing, water immersion or exposure to rain or sunlight
- Remains effective even after bathing
- Remains effective after exposure to rain and sunlight
- Still works after bathing, swimming or exposure to sunlight
- Still works after exposure to sunlight
- Maintains residual efficacy after bathing and swimming
- EFFIPRO® PLUS Topical Solution for Dogs is effective after bathing, shampooing, water immersion, or sunlight exposure.
- Waterproof (remains effective after bathing and swimming)

{Master Label}
Virbac's Master Label

Date December 14, 2011 Version US-8 EPA Reg. No. 2382-XXX
 Fipronil + Pyriproxyfen Topical Solution for Dogs

Virbac
EFFIPRO[®] PLUS TOPICAL SOLUTION FOR DOGS

FOR USE ONLY ON DOGS AND PUPPIES 8 WEEKS OLD OR OLDER (WEIGHING)(UP TO 22.9 LBS, [WEIGHING] 23 TO 44.9 LBS, [WEIGHING] 45 TO 88.9 LBS, [WEIGHING] 89 TO 132 lbs).

ACTIVE INGREDIENTS: 9.7%
 Fipronil 9.7%
 Pyriproxyfen 2.9%
 OTHER INGREDIENTS: 87.4%
 TOTAL: 100.0%

KEEP OUT OF REACH OF CHILDREN
CAUTION
 READ ENTIRE LABEL BEFORE EACH USE

**PRECAUTIONARY STATEMENTS
 HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

HAZARDS TO HUMANS

Harmful if swallowed. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

HAZARDS TO DOMESTIC ANIMALS

For external use only. Do not use on puppies under 8 weeks of age. Individual sensitivities, while rare, may occur after using ANY pesticide product. Possible temporary irritation may occur at the site where EFFIPRO[®] PLUS Topical Solution for Dogs was applied. Contact a veterinarian immediately if signs become persistent or become more severe during the first few days following application. If an unusual reaction is observed following initial application, a veterinarian should be consulted before repeating application. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated or aged dogs.

FIRST AID	
IF SWALLOWED:	<ul style="list-style-type: none"> Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.
IF IN EYES:	<ul style="list-style-type: none"> Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.
IF ON SKIN OR CLOTHING:	<ul style="list-style-type: none"> Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.
Have product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact the Hotline number 1-800-338-3659 for human and veterinary health concerns, emergency medical treatment information or pesticide incidents.	

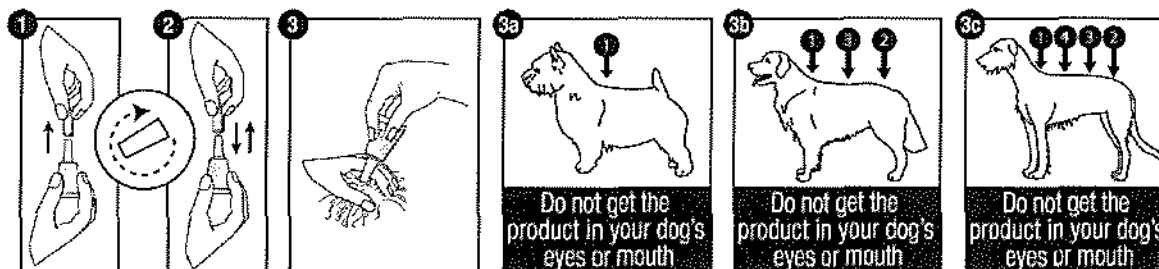
DIRECTIONS FOR USE

It is a violation of Federal law to use this product in any manner inconsistent with its labeling. Do not allow children to apply product. TO PREVENT HARM TO YOU AND YOUR DOG, READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON DOGS ONLY. DO NOT USE ON RABBITS. DO NOT USE ON OTHER ANIMALS.

For killing fleas, flea eggs, flea larvae, all stages of Brown dog ticks, American dog ticks, Lone Star ticks, and Deer ticks (that may [which may] transmit (carry) Lyme disease), mosquitoes and chewing lice; apply to DOGS or PUPPIES (8 weeks old or older) as follows:

APPLICATION DIRECTIONS

1. Remove one applicator from packaging.
Hold applicator upright and remove cap.
2. Invert cap and place other end back onto applicator tip.
Push cap down to break seal.
Remove cap prior to treatment application.
3. Part dog's hair between shoulder blades until skin is visible.
Place applicator tip directly against exposed skin.
- 3a. For small dogs (12 weeks old or older) and weighing up to 22.9 lbs- Deposit entire contents by squeezing the entire applicator contents onto dog's skin, at a single site, between the shoulder blades as shown in diagram 3a.
- 3b. For medium dogs 23-44.9 lbs or large dogs 45-88.9 lbs- Apply the product evenly to three spots on the dog's back, starting between the shoulder blades and continuing on to the second and third spots as shown in diagram 3b, squeezing the applicator until empty.
- 3c. For extra large dogs 89-132 lbs- Apply the product evenly to four spots on the dog's back, starting between the shoulder blades and continuing on to the second, third and fourth spots as shown in diagram 3c, squeezing the applicator until empty. Ensure that EFFIPRO[®] PLUS Topical Solution for Dogs is not applied superficially on dog's hair.



FREQUENCY OF APPLICATION

Research has shown that flea, tick and chewing lice infestations can be controlled with monthly applications of EFFIPRO[®] PLUS Topical Solution for Dogs.

Fleas: EFFIPRO[®] PLUS Topical Solution for Dogs can kill adult fleas for up to three months. Apply monthly if your dog has fleas that may cause Flea Allergy Dermatitis (FAD), or if reinfestation is likely. EFFIPRO[®] PLUS Topical Solution for Dogs can control flea eggs for up to three months (90 days).

Ticks: EFFIPRO[®] PLUS Topical Solution for Dogs can kill ticks for a month or longer. Apply monthly where tick control is consistently needed.

Chewing Lice: EFFIPRO[®] PLUS Topical Solution for Dogs can kill chewing lice for a month or longer. Apply monthly where chewing lice control is consistently needed.

Mosquitoes: When applied monthly, EFFIPRO[®] PLUS Topical Solution for Dogs can kill mosquitoes within 24 hours (for up to 7 days) and within 48 hours (for up to 28 days).

Notes: Wait at least 30 days before re-application of EFFIPRO[®] PLUS Topical Solution for Dogs. Avoid contact with treated area until dry.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

STORAGE: Store unused product in original container only, out of reach of children and animals.

PESTICIDE/CONTAINER DISPOSAL: If empty: Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available. If partially filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

LIMITED WARRANTY AND DISCLAIMER

To the extent consistent with applicable law, buyer assumes all risks of use, storage, or handling of this product not in accordance with directions. Buyer and user assume all risks of use and handling of this material when such use and handling are contrary to label instructions. To the extent consistent with applicable law, any damage arising from a breach of this warranty shall be limited to direct damages and shall not include consequential commercial damages such as loss of profit or values.

How supplied: For easy and convenient application, EFFIPRO® PLUS Topical Solution for Dogs is available in sizes for small dogs and puppies 8 weeks old or older and up to 22.9 lbs (0.023 fl oz)/(0.67 mL), medium dogs 23-44.9 lbs (0.045 fl oz)/(1.34 mL), large dogs 45-88.9 lbs (0.091 fl oz)/(2.68 mL), and extra large dogs 89-132 lbs (0.136 fl oz)/(4.02 mL).

Net Contents:

1, 3, 6 or 36 single-dose applicator(s) per package. Each applicator contains 0.023 fl oz (0.67 mL), 0.045 fl oz (1.34 mL), 0.091 fl oz (2.68 mL), or 0.136 fl oz (4.02 mL) of solution).

(Detachable) calendar (monthly application) reminder stickers (with illustration of dog or puppy)

EPA Reg. No. 2382-xxx

EPA Est. No. 2382-xxxx

VIRBAC AH, INC.
PO BOX 162059
FORT WORTH, TX 76161
1-800-338-3659

Made in France

EFFIPRO® is a registered trademark of Virbac S.A. in the United States

Questions or comments?

Call: 1-800-338-3659

{Text for Front Panel, Back Panel and Side Panel}

See package insert(s) for directions for use and frequency of application

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Open resealable label for directions for use and storage and disposal

See back panel for additional precautionary statements

See package insert(s) for frequency of application

See enclosed insert(s) for directions for use and storage and disposal

See enclosed insert(s) for directions for use

Photograph of dog or puppy

Lift here to open (LIFT HERE TO OPEN)

For Use on Dogs only

Use only on dogs

{Text for Foil of Blister package}

Virbac

EFFIPRO® PLUS Topical Solution for Dogs

Only for use (on dogs up to 22.9 lbs, on dogs 23-44.9 lbs, on dogs 45-88.9 lbs, on dogs 89-132 lbs) / (0.023 fl oz [0.67 mL], 0.045 fl oz [1.34 mL], 0.091 fl oz [2.68 mL], 0.136 fl oz [4.02 mL]).

Contains fipronil (9.7%) and pyriproxyfen (2.9%)

KEEP OUT OF REACH OF CHILDREN

CAUTION

See full label for additional directions

EPA Reg. No. 2382-xxx

{Text for Applicator Tube}

Virbac

EFFIPRO® PLUS

Topical Solution for Dogs

Only for use on dogs

up to 22.9 lbs (23-44.9 lbs, 45-88.9 lbs, 89-132 lbs)

0.023 fl oz [0.67 mL] (0.045 fl oz [1.34 mL], 0.091 fl oz [2.68

mL], 0.136 fl oz [4.02 mL])

Contains fipronil (9.7%) and pyriproxyfen (2.9%)

KEEP OUT OF REACH

OF CHILDREN

CAUTION

See full label for additional directions

EPA Reg. No. 2382-xxx

MARKETING CLAIMS

[Multiple infestations]

- For convenient, quick-acting, long-lasting, effective control of fleas, ticks, mosquitoes and chewing lice.
- For convenient, quick-acting, long-lasting, effective control of fleas, flea eggs, flea larvae, ticks, mosquitoes and chewing lice.
- EFFIPRO® PLUS Topical Solution for Dogs contains the active ingredient fipronil, which controls infestations caused by fleas, ticks, mosquitoes and chewing lice (on dogs) (DOGS or PUPPIES) (8 weeks old or older) (weighing up to 22.9 lbs, weighing 23 to 44.9 lbs, weighing 45 to 88.9 lbs, weighing 89 to 132 lbs).
- EFFIPRO® PLUS Topical Solution for Dogs contains the active ingredient pyriproxyfen, which controls reinfestations caused by flea eggs and flea larvae (on dogs) (DOGS or PUPPIES) (8 weeks old or older) (weighing up to 22.9 lbs, weighing 23 to 44.9 lbs, weighing 45 to 88.9 lbs, weighing 89 to 132 lbs).
- For easy and convenient application, EFFIPRO® PLUS Topical Solution for Dogs is available in sizes for small dogs and puppies 8 weeks old or older and up to 22.9 lbs (0.023 fl oz) (0.67 mL), medium dogs 23-44.9 lbs (0.045 fl oz) (1.34 mL), large dogs 45-88.9 lbs (0.09 fl oz) (2.68 mL), and extra large dogs 89-132 lbs (0.136 fl oz) (4.02 mL).
- For killing fleas, (flea eggs, flea larvae,) all stages of Brown dog ticks, American dog ticks, Lone Star ticks, and Deer ticks (that [which] may transmit [carry] Lyme disease), mosquitoes and chewing lice; apply to DOGS or PUPPIES (8 weeks old or older) as follows: (followed by application directions).
- Persistent flea and tick efficacy for up to one month (4 weeks)
- Prevents flea and tick (re-)infestation for up to one month (4 weeks)
- Kills fleas and ticks for up to one month (4 weeks)
- Apply monthly for control and prevention of fleas and ticks
- Kills fleas and ticks that may transmit Lyme disease, Rocky Mountain Spotted Fever, babesiosis, ehrlichiosis, bartonellosis (and hepatozoonosis).
- Kills fleas, (flea eggs, flea larvae,) ticks, mosquitoes and chewing lice
- Kills fleas, (flea eggs, flea larvae,) ticks, mosquitoes and lice
- Effective monthly control of fleas and ticks
- Effective monthly application for fleas and ticks
- Effective monthly application for dogs against fleas and ticks
- Single application kills fleas and ticks
- Single application lasts 4 weeks (one month)
- Research has shown that flea, tick and chewing lice infestations can be completely controlled with monthly applications of EFFIPRO® PLUS Topical Solution for Dogs.
- Fleas: EFFIPRO® PLUS Topical Solution for Dogs can kill adult fleas, flea eggs and flea larvae for up to three months. Apply monthly if your dog has fleas that may cause Flea Allergy Dermatitis (FAD), or if reinfestation is likely.
- Ticks: EFFIPRO® PLUS Topical Solution for Dogs can kill ticks for a month or longer. Apply monthly where tick control is consistently needed.
- Chewing Lice: EFFIPRO® PLUS Topical Solution for Dogs can kill chewing lice for a month or longer. Apply monthly where chewing lice control is consistently needed.
- Mosquitoes: When applied monthly, EFFIPRO® PLUS Topical Solution for Dogs can kill mosquitoes within 24 hours (for up to 7 days) and within 48 hours (for up to 28 days).

[Fleas]

- Kills newly emerged adult fleas prior to egg laying
- Kills fleas, flea eggs and flea larvae
- Sterilizes and kills (adult) fleas
- Prevents all flea stages (adult fleas, flea eggs, flea pupae and flea larvae)
- Prevents development of all flea stages (flea eggs, flea pupae and flea larvae) for up to (3 months) (90 days)
- With pyriproxyfen (IGR) to break flea life cycle
- Dual Action(!): fipronil and pyriproxyfen (IGR) effectively breaks the flea life cycle
- Kills fleas that may transmit bartonellosis
- Kills fleas that may transmit bartonellosis, tularemia and tapeworm
- Kills fleas that may transmit diseases, including bartonellosis, tularemia (and tapeworm infestations).
- Kills fleas that may cause Flea Allergy Dermatitis (FAD) or flea-bite anemia
- Effective monthly application against fleas
- Effective monthly control of fleas
- Kills adult fleas for up to one month (4 weeks)
- Kills fleas
- Easy to apply, control of (for) fleas that lasts 1 month (4 weeks)
- Easy to apply, flea control that lasts up to 1 (one) month (4 weeks)
- EFFIPRO® PLUS Topical Solution for Dogs kills fleas on your dog
- Kills adult fleas which may cause Flea Allergy Dermatitis (FAD)
- Kills fleas which (that) may cause flea-bite anemia
- Fleas do not have to bite to die
- EFFIPRO® PLUS Topical Solution for Dogs rapidly kills fleas that may cause FAD (Flea Allergy Dermatitis)
- The successive feeding activity of fleas on dogs may elicit a hypersensitivity skin disorder known as Flea Allergy Dermatitis (FAD)
- Prevents flea eggs from hatching or developing into larvae or adult stages (for up to 90 days (3 months))

[Ticks]

- Kills all stages of Brown dog ticks, American dog ticks, Lone Star ticks, and Deer ticks (including those that may transmit Lyme disease, Rocky Mountain Spotted Fever, babesiosis, ehrlichiosis and anaplasmosis)
- Kills ticks including Deer ticks (that may transmit Lyme disease), American dog ticks (that may transmit Rocky Mountain Spotted Fever), Brown dog ticks (that may transmit ehrlichiosis), and Lone Star ticks (that may transmit hepatoparasitosis) for up to one month (4 weeks).
- Kills ticks including Deer ticks (that may transmit Lyme disease), American dog ticks (that may transmit Rocky Mountain Spotted Fever), and Brown dog ticks (that may transmit ehrlichiosis) for up to one month (4 weeks).
- Kills Brown dog ticks (*Rhipicephalus* spp), American dog ticks (*Dermacentor variabilis*), Deer ticks (*Ixodes* spp) and Lone Star ticks (*Amblyomma americanum*) for up to one month (4 weeks).
- Kills *Amblyomma americanum* (Lone Star ticks) for 4 weeks (for up to one month).
- Effective monthly application against ticks

[Mosquitoes]

- Kills mosquitoes
- Kills mosquitoes for up to 28 days

[All others]

- EFFIPRO® PLUS Topical Solution for Dogs aids in (the) control of sarcoptic mange mite infestations.
- Aids in (the) control of sarcoptic mange mite infestations
- Elimination of mites may require multiple monthly applications.
- Chewing lice infestations are rapidly eliminated
- May be used on puppies from 8 weeks of age
- Only for dogs and puppies 8 weeks old or older (weighing up to 22.9 lbs, 23 to 44.9 lbs, weighing 45 to 88.9 lbs, weighing 89 to 132 lbs)
- Easy, spot-on (topical) application
- Convenient topical application for dogs
- Easy to apply spot-on (topical) application
- Quick drying, non-greasy
- Convenient, easy to apply
- Easy and convenient application (applications)
- Convenient to use (easy to apply)
- Once monthly application
- Single application lasts up to 4 weeks (1 month) (one month)
- 1 (3, 6 or 36) applicator(s) [tube(s)] 0.023 fl oz (0.67 mL)
- 1 (3, 6 or 36) applicator(s) [tube(s)] 0.045 fl oz (1.34 mL)
- 1 (3, 6 or 36) applicator(s) [tube(s)] 0.091 fl oz (2.68 mL)
- 1 (3, 6 or 36) applicator(s) [tube(s)] 0.136 fl oz (4.02 mL)
- 1 (3, 6, 36) month(ly) dose(s) (applications)
- 1 (3, 6 or 36) applicator(s) [tube(s)] (each) containing 0.023 fl oz (0.67 mL)
- 1 (3, 6 or 36) applicator(s) [tube(s)] (each) containing 0.045 fl oz (1.34 mL)
- 1 (3, 6 or 36) applicator(s) [tube(s)] (each) containing 0.091 fl oz (2.68 mL)
- 1 (3, 6 or 36) applicator(s) [tube(s)] (each) containing 0.136 fl oz (4.02 mL)
- 1 applicator (tube) 1 month(ly) dose
- 3 applicators (tubes) 3 monthly doses (applications)
- 6 applicators (tubes) 6 monthly doses (applications)
- 36 applicators (tubes) 36 monthly doses (applications)
- 1 (3, 6, 36) applicator(s) containing 0.023 fl oz (0.67 mL), 0.045 fl oz [1.34 mL], 0.091 fl oz [2.68 mL], 0.136 fl oz [4.02 mL]
- Available from licensed veterinarians
- Remains effective after exposure to sunlight
- Remains effective after bathing and swimming
- Remains effective even after bathing, water immersion or exposure to rain or sunlight
- Remains effective even after bathing
- Remains effective after exposure to rain and sunlight
- Still works after bathing, swimming or exposure to sunlight
- Still works after exposure to sunlight
- Maintains residual efficacy after bathing and swimming
- EFFIPRO® PLUS Topical Solution for Dogs is effective after bathing, shampooing, water immersion, or sunlight exposure.
- Waterproof (remains effective after bathing and swimming)

{Master Label}
Virbac's Master Label

Date December 14, 2011 Version US-8 EPA Reg. No. 2382-XXX
 Fipronil + Pyriproxyfen Topical Solution for Dogs

Virbac
EFFIPRO® PLUS TOPICAL SOLUTION FOR DOGS

FOR USE ONLY ON DOGS AND PUPPIES 8 WEEKS OLD OR OLDER (WEIGHING) (UP TO 22.9 LBS, [WEIGHING] 23 TO 44.9 LBS, [WEIGHING] 45 TO 88.9 LBS, [WEIGHING] 89 TO 132 lbs).

ACTIVE INGREDIENTS:
 Fipronil 9.7%
 Pyriproxyfen 2.9%
 OTHER INGREDIENTS: 87.4%
 TOTAL: 100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

READ ENTIRE LABEL BEFORE EACH USE

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

HAZARDS TO HUMANS

Harmful if swallowed. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

HAZARDS TO DOMESTIC ANIMALS

For external use only. Do not use on puppies under 8 weeks of age. Individual sensitivities, while rare, may occur after using ANY pesticide product. Possible temporary irritation may occur at the site where EFFIPRO® PLUS Topical Solution for Dogs was applied. Contact a veterinarian immediately if signs become persistent or become more severe during the first few days following application. If an unusual reaction is observed following initial application, a veterinarian should be consulted before repeating application. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated or aged dogs.

FIRST AID	
IF SWALLOWED:	<ul style="list-style-type: none"> Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.
IF IN EYES:	<ul style="list-style-type: none"> Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.
IF ON SKIN OR CLOTHING:	<ul style="list-style-type: none"> Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.
Have product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact the Hotline number 1-800-338-3659 for human and veterinary health concerns, emergency medical treatment information or pesticide incidents.	

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in any manner inconsistent with its labeling. Do not allow children to apply product. TO PREVENT HARM TO YOU AND YOUR DOG, READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON DOGS ONLY. DO NOT USE ON RABBITS. DO NOT USE ON OTHER ANIMALS.

For killing fleas, flea eggs, flea larvae, all stages of Brown dog ticks, American dog ticks, Lone Star ticks, and Deer ticks (that may [which may] transmit [carry] Lyme disease), mosquitoes and chewing lice; apply to DOGS or PUPPIES (8 weeks old or older) as follows:

APPLICATION DIRECTIONS

1. Remove one applicator from packaging.
Hold applicator upright and remove cap.
2. Invert cap and place other end back onto applicator tip.
Push cap down to break seal.
Remove cap prior to treatment application.
3. Part dog's hair between shoulder blades until skin is visible.
Place applicator tip directly against exposed skin.
- 3a. For small dogs (12 weeks old or older) and weighing up to 22.9 lbs- Deposit entire contents by squeezing the entire applicator contents onto dog's skin, at a single site, between the shoulder blades as shown in diagram 3a.
- 3b. For medium dogs 23-44.9 lbs or large dogs 45-88.9 lbs- Apply the product evenly to three spots on the dog's back, starting between the shoulder blades and continuing on to the second and third spots as shown in diagram 3b, squeezing the applicator until empty.
- 3c. For extra large dogs 89-132 lbs- Apply the product evenly to four spots on the dog's back, starting between the shoulder blades and continuing on to the second, third and fourth spots as shown in diagram 3c, squeezing the applicator until empty. Ensure that EFFIPRO® PLUS Topical Solution for Dogs is not applied superficially on dog's hair.



FREQUENCY OF APPLICATION

Research has shown that flea, tick and chewing lice infestations can be controlled with monthly applications of EFFIPRO® PLUS Topical Solution for Dogs.

Fleas: EFFIPRO® PLUS Topical Solution for Dogs can kill adult fleas for up to three months. Apply monthly if your dog has fleas that may cause Flea Allergy Dermatitis (FAD), or if reinfestation is likely. EFFIPRO® PLUS Topical Solution for Dogs can control flea eggs for up to three months (90 days).

Ticks: EFFIPRO® PLUS Topical Solution for Dogs can kill ticks for a month or longer. Apply monthly where tick control is consistently needed.

Chewing Lice: EFFIPRO® PLUS Topical Solution for Dogs can kill chewing lice for a month or longer. Apply monthly where chewing lice control is consistently needed.

Mosquitoes: When applied monthly, EFFIPRO® PLUS Topical Solution for Dogs can kill mosquitoes within 24 hours (for up to 7 days) and within 48 hours (for up to 28 days).

Notes: Wait at least 30 days before re-application of EFFIPRO® PLUS Topical Solution for Dogs. Avoid contact with treated area until dry.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

STORAGE: Store unused product in original container only, out of reach of children and animals.

PESTICIDE/CONTAINER DISPOSAL: If empty: Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available. If partially filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

LIMITED WARRANTY AND DISCLAIMER

To the extent consistent with applicable law, buyer assumes all risks of use, storage, or handling of this product not in accordance with directions. Buyer and user assume all risks of use and handling of this material when such use and handling are contrary to label instructions. To the extent consistent with applicable law, any damage arising from a breach of this warranty shall be limited to direct damages and shall not include consequential commercial damages such as loss of profit or values.

How supplied: For easy and convenient application, EFFIPRO® PLUS Topical Solution for Dogs is available in sizes for small dogs and puppies 8 weeks old or older and up to 22.9 lbs (0.023 fl oz)/(0.67 mL), medium dogs 23-44.9 lbs (0.045 fl oz)/(1.34 mL), large dogs 45-88.9 lbs (0.091 fl oz)/(2.68 mL), and extra large dogs 89-132 lbs (0.136 fl oz)/(4.02 mL).

Net Contents:

1, 3, 6 or 36 single-dose applicator(s) per package. Each applicator contains 0.023 fl oz (0.67 mL), 0.045 fl oz (1.34 mL), 0.091 fl oz (2.68 mL), or 0.136 fl oz (4.02 mL) of solution).

(Detachable) calendar (monthly application) reminder stickers (with illustration of dog or puppy)

EPA Reg. No. 2382-xxx

EPA Est. No. 2382-xxxx

VIRBAC AH, INC.
PO BOX 162059
FORT WORTH, TX 76161
1-800-338-3659

Made in France

EFFIPRO® is a registered trademark of Virbac S.A. in the United States

Questions or comments?

Call: 1-800-338-3659

{Text for Front Panel, Back Panel and Side Panel}

See package insert(s) for directions for use and frequency of application

Open resealable label for directions for use

Open resealable label for directions for use and storage and disposal

See back panel for additional precautionary statements

See package insert(s) for frequency of application

See enclosed insert(s) for directions for use and storage and disposal

See enclosed insert(s) for directions for use

Photograph of dog or puppy

Lift here to open (LIFT HERE TO OPEN)

For Use on Dogs only

Use only on dogs

{Text for Foil of Blister package}

Virbac

EFFIPRO® PLUS Topical Solution for Dogs

Only for use (on dogs up to 22.9 lbs, on dogs 23-44.9 lbs, on dogs 45-88.9 lbs, on dogs 89-132 lbs) / (0.023 fl oz [0.67 mL], 0.045 fl oz [1.34 mL], 0.091 fl oz [2.68 mL], 0.136 fl oz [4.02 mL]).

Contains fipronil (9.7%) and pyriproxyfen (2.9%)

KEEP OUT OF REACH OF CHILDREN

CAUTION

See full label for additional directions

EPA Reg. No. 2382-xxx

{Text for Applicator Tube}

Virbac

EFFIPRO® PLUS

Topical Solution for Dogs

Only for use on dogs

up to 22.9 lbs (23-44.9 lbs, 45-88.9 lbs, 89-132 lbs)

0.023 fl oz [0.67 mL] (0.045 fl oz [1.34 mL], 0.091 fl oz [2.68 mL], 0.136 fl oz [4.02 mL])

Contains fipronil (9.7%) and pyriproxyfen (2.9%)

KEEP OUT OF REACH

OF CHILDREN

CAUTION

See full label for additional directions

EPA Reg. No. 2382-xxx

MARKETING CLAIMS

[Multiple infestations]

- For convenient, quick-acting, long-lasting, effective control of fleas, ticks, mosquitoes and chewing lice.
 - For convenient, quick-acting, long-lasting, effective control of fleas, flea eggs, flea larvae, ticks, mosquitoes and chewing lice.
 - EFFIPRO® PLUS Topical Solution for Dogs contains the active ingredient fipronil, which controls infestations caused by fleas, ticks, mosquitoes and chewing lice (on dogs) (DOGS or PUPPIES) (8 weeks old or older) (weighing up to 22.9 lbs, weighing 23 to 44.9 lbs, weighing 45 to 88.9 lbs, weighing 89 to 132 lbs).
 - EFFIPRO® PLUS Topical Solution for Dogs contains the active ingredient pyriproxyfen, which controls reinfestations caused by flea eggs and flea larvae (on dogs) (DOGS or PUPPIES) (8 weeks old or older) (weighing up to 22.9 lbs, weighing 23 to 44.9 lbs, weighing 45 to 88.9 lbs, weighing 89 to 132 lbs).
 - For easy and convenient application, EFFIPRO® PLUS Topical Solution for Dogs is available in sizes for small dogs and puppies 8 weeks old or older and up to 22.9 lbs (0.023 fl oz) (0.67 mL), medium dogs 23-44.9 lbs (0.045 fl oz) (1.34 mL), large dogs 45-88.9 lbs (0.09 fl oz) (2.68 mL), and extra large dogs 89-132 lbs (0.136 fl oz) (4.02 mL).
 - For killing fleas, (flea eggs, flea larvae,) all stages of Brown dog ticks, American dog ticks, Lone Star ticks, and Deer ticks (that [which] may transmit [carry] Lyme disease), mosquitoes and chewing lice: apply to DOGS or PUPPIES (8 weeks old or older) as follows: (followed by application directions).
 - Persistent flea and tick efficacy for up to one month (4 weeks)
 - Prevents flea and tick (re-)infestation for up to one month (4 weeks)
 - Kills fleas and ticks for up to one month (4 weeks)
 - Apply monthly for control and prevention of fleas and ticks
 - Kills fleas and ticks that may transmit Lyme disease, Rocky Mountain Spotted Fever, babesiosis, ehrlichiosis, bartonellosis (and hepatozoonosis).
 - Kills fleas, (flea eggs, flea larvae,) ticks, mosquitoes and chewing lice
 - Kills fleas, (flea eggs, flea larvae,) ticks, mosquitoes and lice
 - Effective monthly control of fleas and ticks
 - Effective monthly application for fleas and ticks
 - Effective monthly application for dogs against fleas and ticks
 - Single application kills fleas and ticks
 - Single application lasts 4 weeks (one month)
 - Research has shown that flea, tick and chewing lice infestations can be completely controlled with monthly applications of EFFIPRO® PLUS Topical Solution for Dogs.
- Fleas: EFFIPRO® PLUS Topical Solution for Dogs can kill adult fleas, flea eggs and flea larvae for up to three months. Apply monthly if your dog has fleas that may cause Flea Allergy Dermatitis (FAD), or if reinfestation is likely.
- Ticks: EFFIPRO® PLUS Topical Solution for Dogs can kill ticks for a month or longer. Apply monthly where tick control is consistently needed.
- Chewing Lice: EFFIPRO® PLUS Topical Solution for Dogs can kill chewing lice for a month or longer. Apply monthly where chewing lice control is consistently needed.
- Mosquitoes: When applied monthly, EFFIPRO® PLUS Topical Solution for Dogs can kill mosquitoes within 24 hours (for up to 7 days) and within 48 hours (for up to 28 days).

[Fleas]

- Kills newly emerged adult fleas prior to egg laying
- Kills fleas, flea eggs and flea larvae
- Sterilizes and kills (adult) fleas
- Prevents all flea stages (adult fleas, flea eggs, flea pupae and flea larvae)
- Prevents development of all flea stages (flea eggs, flea pupae and flea larvae) for up to (3 months) (90 days)
- With pyriproxyfen (IGR) to break flea life cycle
- Dual Action(!): fipronil and pyriproxyfen (IGR) effectively breaks the flea life cycle
- Kills fleas that may transmit bartonellosis
- Kills fleas that may transmit bartonellosis, tularemia and tapeworm
- Kills fleas that may transmit diseases, including bartonellosis, tularemia (and tapeworm infestations).
- Kills fleas that may cause Flea Allergy Dermatitis (FAD) or flea-bite anemia
- Effective monthly application against fleas
- Effective monthly control of fleas
- Kills adult fleas for up to one month (4 weeks)
- Kills fleas
- Easy to apply, control of (for) fleas that lasts 1 month (4 weeks)
- Easy to apply, flea control that lasts up to 1 (one) month (4 weeks)
- EFFIPRO® PLUS Topical Solution for Dogs kills fleas on your dog
- Kills adult fleas which may cause Flea Allergy Dermatitis (FAD)
- Kills fleas which (that) may cause flea-bite anemia
- Fleas do not have to bite to die
- EFFIPRO® PLUS Topical Solution for Dogs rapidly kills fleas that may cause FAD (Flea Allergy Dermatitis)
- The successive feeding activity of fleas on dogs may elicit a hypersensitivity skin disorder known as Flea Allergy Dermatitis (FAD)
- Prevents flea eggs from hatching or developing into larvae or adult stages (for up to 90 days (3 months))

[Ticks]

- Kills all stages of Brown dog ticks, American dog ticks, Lone Star ticks, and Deer ticks (including those that may transmit Lyme disease, Rocky Mountain Spotted Fever, babesiosis, ehrlichiosis and anaplasmosis)
- Kills ticks including Deer ticks (that may transmit Lyme disease), American dog ticks (that may transmit Rocky Mountain Spotted Fever), Brown dog ticks (that may transmit ehrlichiosis), and Lone Star ticks (that may transmit hepatzoonosis) for up to one month (4 weeks).
- Kills ticks including Deer ticks (that may transmit Lyme disease), American dog ticks (that may transmit Rocky Mountain Spotted Fever), and Brown dog ticks (that may transmit ehrlichiosis) for up to one month (4 weeks).
- Kills Brown dog ticks (*Rhipicephalus* spp), American dog ticks (*Dermacentor variabilis*), Deer ticks (*Ixodes* spp) and Lone Star ticks (*Amblyomma americanum*) for up to one month (4 weeks).
- Kills *Amblyomma americanum* (Lone Star ticks) for 4 weeks (for up to one month).
- Effective monthly application against ticks

(Mosquitoes)

- Kills mosquitoes
- Kills mosquitoes for up to 28 days

(All others)

- EFFIPRO[®] PLUS Topical Solution for Dogs aids in (the) control of sarcoptic mange mite infestations.
- Aids in (the) control of sarcoptic mange mite infestations
- Elimination of mites may require multiple monthly applications.
- Chewing lice infestations are rapidly eliminated
- May be used on puppies from 8 weeks of age
- Only for dogs and puppies 8 weeks old or older (weighing up to 22.9 lbs, 23 to 44.9 lbs, weighing 45 to 88.9 lbs, weighing 89 to 132 lbs)
- Easy, spot-on (topical) application
- Convenient topical application for dogs
- Easy to apply spot-on (topical) application
- Quick drying, non-greasy
- Convenient, easy to apply
- Easy and convenient application (applications)
- Convenient to use (easy to apply)
- Once monthly application
- Single application lasts up to 4 weeks (1 month) (one month)
- 1 (3, 6 or 36) applicator(s) (tube(s)) 0.023 fl oz (0.67 mL)
- 1 (3, 6 or 36) applicator(s) (tube(s)) 0.045 fl oz (1.34 mL)
- 1 (3, 6 or 36) applicator(s) (tube(s)) 0.091 fl oz (2.68 mL)
- 1 (3, 6 or 36) applicator(s) (tube(s)) 0.136 fl oz (4.02 mL)
- 1 (3, 6, 36) month(ly) dose(s) (applications)
- 1 (3, 6 or 36) applicator(s) [tube(s)] (each) containing 0.023 fl oz (0.67 mL)
- 1 (3, 6 or 36) applicator(s) [tube(s)] (each) containing 0.045 fl oz (1.34 mL)
- 1 (3, 6 or 36) applicator(s) [tube(s)] (each) containing 0.091 fl oz (2.68 mL)
- 1 (3, 6 or 36) applicator(s) (tube(s)) (each) containing 0.136 fl oz (4.02 mL)
- 1 applicator (tube) 1 month(ly) dose
- 3 applicators (tubes) 3 monthly doses (applications)
- 6 applicators (tubes) 6 monthly doses (applications)
- 36 applicators (tubes) 36 monthly doses (applications)
- 1 (3, 6, 36) applicator(s) containing 0.023 fl oz (0.67 mL), 0.045 fl oz (1.34 mL), 0.091 fl oz (2.68 mL), 0.136 fl oz (4.02 mL))
- Available from licensed veterinarians
- Remains effective after exposure to sunlight
- Remains effective after bathing and swimming
- Remains effective even after bathing, water immersion or exposure to rain or sunlight
- Remains effective even after bathing
- Remains effective after exposure to rain and sunlight
- Still works after bathing, swimming or exposure to sunlight
- Still works after exposure to sunlight
- Maintains residual efficacy after bathing and swimming
- EFFIPRO[®] PLUS Topical Solution for Dogs is effective after bathing, shampooing, water immersion, or sunlight exposure.
- Waterproof (remains effective after bathing and swimming)

{Master Label}
Virbac's Master Label

Date December 14, 2011 Version US-8 EPA Reg. No. 2382-XXX
 Fipronil + Pyriproxyfen Topical Solution for Dogs

Virbac
EFFIPRO[®] PLUS TOPICAL SOLUTION FOR DOGS

FOR USE ONLY ON DOGS AND PUPPIES 8 WEEKS OLD OR OLDER (WEIGHING) (UP TO 22.9 LBS, [WEIGHING] 23 TO 44.9 LBS, [WEIGHING] 45 TO 88.9 LBS, [WEIGHING] 89 TO 132 lbs).

ACTIVE INGREDIENTS:

Fipronil	9.7%
Pyriproxyfen.....	2.9%
OTHER INGREDIENTS:	87.4%
TOTAL:	100.0%

KEEP OUT OF REACH OF CHILDREN
CAUTION
 READ ENTIRE LABEL BEFORE EACH USE

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

HAZARDS TO HUMANS

Harmful if swallowed. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

HAZARDS TO DOMESTIC ANIMALS

For external use only. Do not use on puppies under 8 weeks of age. Individual sensitivities, while rare, may occur after using ANY pesticide product. Possible temporary irritation may occur at the site where EFFIPRO[®] PLUS Topical Solution for Dogs was applied. Contact a veterinarian immediately if signs become persistent or become more severe during the first few days following application. If an unusual reaction is observed following initial application, a veterinarian should be consulted before repeating application. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated or aged dogs.

FIRST AID	
IF SWALLOWED:	<ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by a poison control center or doctor. • Do not give anything by mouth to an unconscious person.
IF IN EYES:	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
IF ON SKIN OR CLOTHING:	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
Have product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact the Hotline number 1-800-338-3659 for human and veterinary health concerns, emergency medical treatment information or pesticide incidents.	

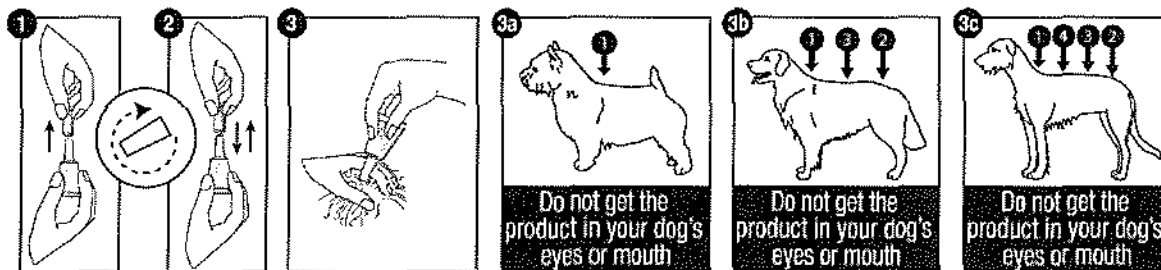
DIRECTIONS FOR USE

It is a violation of Federal law to use this product in any manner inconsistent with its labeling. Do not allow children to apply product. TO PREVENT HARM TO YOU AND YOUR DOG, READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON DOGS ONLY. DO NOT USE ON RABBITS. DO NOT USE ON OTHER ANIMALS.

For killing fleas, flea eggs, flea larvae, all stages of Brown dog ticks, American dog ticks, Lone Star ticks, and Deer ticks (that may [which may] transmit [carry] Lyme disease), mosquitoes and chewing lice; apply to DOGS or PUPPIES (8 weeks old or older) as follows:

APPLICATION DIRECTIONS

1. Remove one applicator from packaging.
Hold applicator upright and remove cap.
2. Invert cap and place other end back onto applicator tip.
Push cap down to break seal.
Remove cap prior to treatment application.
3. Part dog's hair between shoulder blades until skin is visible.
Place applicator tip directly against exposed skin.
- 3a. For small dogs (12 weeks old or older) and weighing up to 22.9 lbs- Deposit entire contents by squeezing the entire applicator contents onto dog's skin, at a single site, between the shoulder blades as shown in diagram 3a.
- 3b. For medium dogs 23-44.9 lbs or large dogs 45-88.9 lbs- Apply the product evenly to three spots on the dog's back, starting between the shoulder blades and continuing on to the second and third spots as shown in diagram 3b, squeezing the applicator until empty.
- 3c. For extra large dogs 89-132 lbs- Apply the product evenly to four spots on the dog's back, starting between the shoulder blades and continuing on to the second, third and fourth spots as shown in diagram 3c, squeezing the applicator until empty. Ensure that EFFIPRO® PLUS Topical Solution for Dogs is not applied superficially on dog's hair.



FREQUENCY OF APPLICATION

Research has shown that flea, tick and chewing lice infestations can be controlled with monthly applications of EFFIPRO® PLUS Topical Solution for Dogs.

Fleas: EFFIPRO® PLUS Topical Solution for Dogs can kill adult fleas for up to three months. Apply monthly if your dog has fleas that may cause Flea Allergy Dermatitis (FAD), or if reinfestation is likely. EFFIPRO® PLUS Topical Solution for Dogs can control flea eggs for up to three months (90 days).

Ticks: EFFIPRO® PLUS Topical Solution for Dogs can kill ticks for a month or longer. Apply monthly where tick control is consistently needed.

Chewing Lice: EFFIPRO® PLUS Topical Solution for Dogs can kill chewing lice for a month or longer. Apply monthly where chewing lice control is consistently needed.

Mosquitoes: When applied monthly, EFFIPRO® PLUS Topical Solution for Dogs can kill mosquitoes within 24 hours (for up to 7 days) and within 48 hours (for up to 28 days).

Notes: Wait at least 30 days before re-application of EFFIPRO® PLUS Topical Solution for Dogs. Avoid contact with treated area until dry.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

STORAGE: Store unused product in original container only, out of reach of children and animals.

PESTICIDE/CONTAINER DISPOSAL: If empty: Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available. If partially filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

LIMITED WARRANTY AND DISCLAIMER

To the extent consistent with applicable law, buyer assumes all risks of use, storage, or handling of this product not in accordance with directions. Buyer and user assume all risks of use and handling of this material when such use and handling are contrary to label instructions. To the extent consistent with applicable law, any damage arising from a breach of this warranty shall be limited to direct damages and shall not include consequential commercial damages such as loss of profit or values.

How supplied: For easy and convenient application, EFFIPRO® PLUS Topical Solution for Dogs is available in sizes for small dogs and puppies 8 weeks old or older and up to 22.9 lbs (0.023 fl oz)/(0.67 mL), medium dogs 23-44.9 lbs (0.045 fl oz)/(1.34 mL), large dogs 45-88.9 lbs (0.09 fl oz)/(2.68 mL), and extra large dogs 89-132 lbs (0.136 fl oz)/(4.02 mL).

Net Contents:

1, 3, 6 or 36 single-dose applicator(s) per package. Each applicator contains 0.023 fl oz (0.67 mL), 0.045 fl oz (1.34 mL), 0.09 fl oz (2.68 mL), or 0.136 fl oz (4.02 mL) (of solution).

(Detachable) calendar (monthly application) reminder stickers (with illustration of dog or puppy)

EPA Reg. No. 2382-xxx

EPA Est. No. 2382-xxxx

VIRBAC AH, INC.
PO BOX 162059
FORT WORTH, TX 76161
1-800-338-3659

Made in France

EFFIPRO® is a registered trademark of Virbac S.A. in the United States

Questions or comments?

Call: 1-800-338-3659

{Text for Front Panel, Back Panel and Side Panel}

See package insert(s) for directions for use and frequency of application

Open resealable label for directions for use

Open resealable label for directions for use and storage and disposal

See back panel for additional precautionary statements

See package insert(s) for frequency of application

See enclosed insert(s) for directions for use and storage and disposal

See enclosed insert(s) for directions for use

Photograph of dog or puppy

Lift here to open (LIFT HERE TO OPEN)

For Use on Dogs only

Use only on dogs

{Text for Foil of Blister package}

Virbac

EFFIPRO® PLUS Topical Solution for Dogs

Only for use (on dogs up to 22.9 lbs, on dogs 23-44.9 lbs, on dogs 45-88.9 lbs, on dogs 89-132 lbs) / (0.023 fl oz [0.67 mL], 0.045 fl oz [1.34 mL], 0.09 fl oz [2.68 mL], 0.136 fl oz [4.02 mL]).

Contains fipronil (9.7%) and pyriproxyfen (2.9%)

KEEP OUT OF REACH OF CHILDREN

CAUTION

See full label for additional directions

EPA Reg. No. 2382-xxx

{Text for Applicator Tube}

Virbac

EFFIPRO® PLUS

Topical Solution for Dogs

Only for use on dogs

up to 22.9 lbs (23-44.9 lbs, 45-88.9 lbs, 89-132 lbs)

0.023 fl oz [0.67 mL] (0.045 fl oz [1.34 mL], 0.09 fl oz [2.68 mL], 0.136 fl oz [4.02 mL])

Contains fipronil (9.7%) and pyriproxyfen (2.9%)

KEEP OUT OF REACH

OF CHILDREN

CAUTION

See full label for additional directions

EPA Reg. No. 2382-xxx

MARKETING CLAIMS

[Multiple infestations]

- For convenient, quick-acting, long-lasting, effective control of fleas, ticks, mosquitoes and chewing lice.
- For convenient, quick-acting, long-lasting, effective control of fleas, flea eggs, flea larvae, ticks, mosquitoes and chewing lice.
- EFFIPRO[®] PLUS Topical Solution for Dogs contains the active ingredient fipronil, which controls infestations caused by fleas, ticks, mosquitoes and chewing lice (on dogs) (DOGS or PUPPIES) (8 weeks old or older) (weighing up to 22.9 lbs, weighing 23 to 44.9 lbs, weighing 45 to 88.9 lbs, weighing 89 to 132 lbs).
- EFFIPRO[®] PLUS Topical Solution for Dogs contains the active ingredient pyriproxyfen, which controls reinfestations caused by fleas eggs and flea larvae (on dogs) (DOGS or PUPPIES) (8 weeks old or older) (weighing up to 22.9 lbs, weighing 23 to 44.9 lbs, weighing 45 to 88.9 lbs, weighing 89 to 132 lbs).
- For easy and convenient application, EFFIPRO[®] PLUS Topical Solution for Dogs is available in sizes for small dogs and puppies 8 weeks old or older and up to 22.9 lbs (0.023 fl oz) (0.67 mL), medium dogs 23-44.9 lbs (0.045 fl oz) (1.34 mL), large dogs 45-88.9 lbs (0.091 fl oz) (2.68 mL), and extra large dogs 89-132 lbs (0.136 fl oz) (4.02 mL).
- For killing fleas, (flea eggs, flea larvae,) all stages of Brown dog ticks, American dog ticks, Lone Star ticks, and Deer ticks (that [which] may transmit [carry] Lyme disease), mosquitoes and chewing lice; apply to DOGS or PUPPIES (8 weeks old or older) as follows: (followed by application directions).
- Persistent flea and tick efficacy for up to one month (4 weeks)
- Prevents flea and tick (re-)infestation for up to one month (4 weeks)
- Kills fleas and ticks for up to one month (4 weeks)
- Apply monthly for control and prevention of fleas and ticks
- Kills fleas and ticks that may transmit Lyme disease, Rocky Mountain Spotted Fever, babesiosis, ehrlichiosis, bartonellosis (and hepatozoonosis).
- Kills fleas, (flea eggs, flea larvae,) ticks, mosquitoes and chewing lice
- Kills fleas, (flea eggs, flea larvae,) ticks, mosquitoes and lice
- Effective monthly control of fleas and ticks
- Effective monthly application for fleas and ticks
- Effective monthly application for dogs against fleas and ticks
- Single application kills fleas and ticks
- Single application lasts 4 weeks (one month)
- Research has shown that flea, tick and chewing lice infestations can be completely controlled with monthly applications of EFFIPRO[®] PLUS Topical Solution for Dogs.
- Fleas: EFFIPRO[®] PLUS Topical Solution for Dogs can kill adult fleas, flea eggs and flea larvae for up to three months. Apply monthly if your dog has fleas that may cause Flea Allergy Dermatitis (FAD), or if reinfestation is likely.
- Ticks: EFFIPRO[®] PLUS Topical Solution for Dogs can kill ticks for a month or longer. Apply monthly where tick control is consistently needed.
- Chewing Lice: EFFIPRO[®] PLUS Topical Solution for Dogs can kill chewing lice for a month or longer. Apply monthly where chewing lice control is consistently needed.
- Mosquitoes: When applied monthly, EFFIPRO[®] PLUS Topical Solution for Dogs can kill mosquitoes within 24 hours (for up to 7 days) and within 48 hours (for up to 28 days).

[Fleas]

- Kills newly emerged adult fleas prior to egg laying
- Kills fleas, flea eggs and flea larvae
- Sterilizes and kills (adult) fleas
- Prevents all flea stages (adult fleas, flea eggs, flea pupae and flea larvae)
- Prevents development of all flea stages (flea eggs, flea pupae and flea larvae) for up to (3 months) (90 days)
- With pyriproxyfen (IGR) to break flea life cycle
- Dual Action(!): fipronil and pyriproxyfen (IGR) effectively breaks the flea life cycle
- Kills fleas that may transmit bartonellosis
- Kills fleas that may transmit bartonellosis, tularemia and tapeworm
- Kills fleas that may transmit diseases, including bartonellosis, tularemia (and tapeworm infestations).
- Kills fleas that may cause Flea Allergy Dermatitis (FAD) or flea-bite anemia
- Effective monthly application against fleas
- Effective monthly control of fleas
- Kills adult fleas for up to one month (4 weeks)
- Kills fleas
- Easy to apply, control of (for) fleas that lasts 1 month (4 weeks)
- Easy to apply, flea control that lasts up to 1 (one) month (4 weeks)
- EFFIPRO[®] PLUS Topical Solution for Dogs kills fleas on your dog
- Kills adult fleas which may cause Flea Allergy Dermatitis (FAD)
- Kills fleas which (that) may cause flea-bite anemia
- Fleas do not have to bite to die
- EFFIPRO[®] PLUS Topical Solution for Dogs rapidly kills fleas that may cause FAD (Flea Allergy Dermatitis)
- The successive feeding activity of fleas on dogs may elicit a hypersensitivity skin disorder known as Flea Allergy Dermatitis (FAD)
- Prevents flea eggs from hatching or developing into larvae or adult stages (for up to 90 days (3 months))

[Ticks]

- Kills all stages of Brown dog ticks, American dog ticks, Lone Star ticks, and Deer ticks (including those that may transmit Lyme disease, Rocky Mountain Spotted Fever, babesiosis, ehrlichiosis and anaplasmosis)
- Kills ticks including Deer ticks (that may transmit Lyme disease), American dog ticks (that may transmit Rocky Mountain Spotted Fever), Brown dog ticks (that may transmit ehrlichiosis), and Lone Star ticks (that may transmit hepatzoonosis) for up to one month (4 weeks).
- Kills ticks including Deer ticks (that may transmit Lyme disease), American dog ticks (that may transmit Rocky Mountain Spotted Fever), and Brown dog ticks (that may transmit ehrlichiosis) for up to one month (4 weeks).
- Kills Brown dog ticks (*Rhipicephalus* spp), American dog ticks (*Dermacentor variabilis*), Deer ticks (*Ixodes* spp) and Lone Star ticks (*Amblyomma americanum*) for up to one month (4 weeks).
- Kills *Amblyomma americanum* (Lone Star ticks) for 4 weeks (for up to one month).
- Effective monthly application against ticks

[Mosquitoes]

- Kills mosquitoes
- Kills mosquitoes for up to 28 days

[All others]

- EFFIPRO® PLUS Topical Solution for Dogs aids in (the) control of sarcoptic mange mite infestations.
- Aids in (the) control of sarcoptic mange mite infestations
- Elimination of mites may require multiple monthly applications.
- Chewing lice infestations are rapidly eliminated
- May be used on puppies from 8 weeks of age
- Only for dogs and puppies 8 weeks old or older (weighing up to 22.9 lbs, 23 to 44.9 lbs, weighing 45 to 88.9 lbs, weighing 89 to 132 lbs)
- Easy, spot-on (topical) application
- Convenient topical application for dogs
- Easy to apply spot-on (topical) application
- Quick drying, non-greasy
- Convenient, easy to apply
- Easy and convenient application (applications)
- Convenient to use (easy to apply)
- Once monthly application
- Single application lasts up to 4 weeks (1 month) (one month)
- t (3, 6 or 36) applicator(s) [tube(s)] 0.023 fl oz (0.67 mL)
- t (3, 6 or 36) applicator(s) [tube(s)] 0.045 fl oz (1.34 mL)
- t (3, 6 or 36) applicator(s) [tube(s)] 0.091 fl oz (2.68 mL)
- t (3, 6 or 36) applicator(s) [tube(s)] 0.136 fl oz (4.02 mL)
- t (3, 6, 36) month(ly) dose(s) (applications)
- 1 (3, 6 or 36) applicator(s) [tube(s)] (each) containing 0.023 fl oz (0.67 mL)
- 1 (3, 6 or 36) applicator(s) [tube(s)] (each) containing 0.045 fl oz (1.34 mL)
- 1 (3, 6 or 36) applicator(s) [tube(s)] (each) containing 0.091 fl oz (2.68 mL)
- 1 (3, 6 or 36) applicator(s) [tube(s)] (each) containing 0.136 fl oz (4.02 mL)
- t applicator (tube) 1 month(ly) dose
- 3 applicators (tubes) 3 monthly doses (applications)
- 6 applicators (tubes) 6 monthly doses (applications)
- 36 applicators (tubes) 36 monthly doses (applications)
- t (3, 6, 36) applicator(s) containing 0.023 fl oz [0.67 mL], (0.045 fl oz [1.34 mL], 0.091 fl oz [2.68 mL], 0.136 fl oz [4.02 mL])
- Available from licensed veterinarians
- Remains effective after exposure to sunlight
- Remains effective after bathing and swimming
- Remains effective even after bathing, water immersion or exposure to rain or sunlight
- Remains effective even after bathing
- Remains effective after exposure to rain and sunlight
- Still works after bathing, swimming or exposure to sunlight
- Still works after exposure to sunlight
- Maintains residual efficacy after bathing and swimming
- EFFIPRO® PLUS Topical Solution for Dogs is effective after bathing, shampooing, water immersion, or sunlight exposure.
- Waterproof (remains effective after bathing and swimming)



VIRBAC rebuttal to the TRB review for 2382-RII dated 5-18-12

Byron Backus to: Richard Gebken

06/20/2012 04:10 PM

Cc: John Redden, Masih Hashim

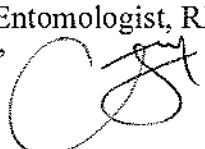
History: This message has been forwarded.

After reviewing Virbac's rebuttal dated June 11, 2012, I have concluded that the MRIDs previously cited in support of EPA File Symbol 2382-RII will allow a claim for use on 8-week-old kittens. In addition, it is noted that 2382-RII is similar to 2382-186, except that 2382-RII includes 11.5% Pyriproxyfen, which has very low toxicity to mammalian species.

Efficacy Review

Date: June 19, 2012

Efficacy Reviewer: Clayton Myers, Ph.D., Entomologist, RD-IB
myers.clayton@epa.gov
703-347-8874

 6-19-12

Risk Manager Rev.: Bonaventure Akinlosotu

Products: EFFIPRO Plus Topical Solution for Dogs

EPA Reg. #: 2382-RIO

A.I.'s: Fipronil (9.7%), Pyriproxyfen (2.9%)

Decision #s: 459013

DP #s: 398342

Submission: R310, New Products, RD Science Review

MRIDs: Submitted: 48696915, 48695015, 48695016, 48695017

Cited: 43121114, 43121115, 43121116, 43121117, 43121118, 43121119,
43121120, 43121121, 43121122, 43444901, 43577701, 43577712,
43577713, 43951701, 44088901, 46006002, 44900904, 45020601,
44942011, 44942106, 45612701, 45618501, 45620501, 45620502,
45620503, 45620504, 45620505, 45620506, 45628101, 45628102,
45628103, 45628104, 45628105, 45628201, 45866901, 45866902,
46019201, 46019202,

GLP: Not all

Summary/Discussion of Submitted and Cited Efficacy Data:

Efficacy claims are supported for control the following pests on dogs for one month:

1. Fleas (adults, eggs, and larvae). A six week duration claim is supported for flea adults, as it is caveated that treatment should be applied every four weeks under high flea pressure (same as claims accepted for pioneer fipronil products). Claims against flea eggs, flea larvae, prevention of all flea life stages, and breaking of the flea life cycle are supported for 3 months (90 days).
2. Ticks (all stages, including Ticks that may transmit Lyme Disease)
3. Mosquitoes
4. Chewing Lice
5. Aids in Control of Sarcoptic Mange

6. Submitted MRID's are summaries and/or extraneous to data requirements and are rated as supplemental.

Specific Review of Label Claims and Directions:

1. Throughout the label, for the mosquito claims related to speed of kill, "Kills mosquitoes within 24 hours for up to 7 days and within 48 hours for up to 28 days", all parentheses must be removed, as this implies optional text for the durations of control.
2. Throughout the label, all references to disease claims which are open ended must be revised to only refer to specific diseases that may be transmitted by the targeted pest. For example, all text that can be interpreted as all-inclusive such as "including" prior to a list of diseases must be deleted.

Explore Registrations

Reg Number: 2382-RIO Reg. Type: Product Registration - Section 3 Status: Under Review (20-Dec-2011)

Name: EFFIPRO PLUS TOPICAL SOLUTION FOR DOGS <View Registration Details>

(No New Receipts)

S	Submission Type	OPP Rec'd Date	Resubmission	Description

...Decisions...

- Data Requirements
- D: Pending; 459013; 2382-RID; R310; NEW PRD.
- 75-Day Letters
- S: 908748; 12/20/2011: New Registration

S: 908748 Reg #: 2382-RIO

Submission Type: New Registration

Resubmission?: ☐ Yes ☒ No E-Sub #:

Decision #: 459013; R310; NEW PRODUCT; NON-FAST TRACK (INCLUDE:

Submitter Company: VIRBAC AH, INC.

Application Date: 19-Dec-2011

OPP Received Date: 20-Dec-2011 Date Sent to Risk manager: 22-Dec-2011

Studies Included?: ☐ Yes ☒ No Fast Track?: ☐ Yes ☒ No

Form A Signed?: ☐ Yes ☐ No ☒ None Date:

Form B Signed?: ☐ Yes ☐ No ☒ None Date:

Reviewer: Akinlosotu, Bonaventure

Received DT: Editable Due DT:

Submission Due DT: 10-Jul-2012 Response: 0, 20-Dec-2011

Priority Weight: Priority Points:

Comments: New Registration

9.7% Aipamid
2.9% Pyriproxyfen

Spot-on for dogs

- Selective Citation

- Submits prod Chem, Tox(PL, Efb, CAS; Cites CPP data

- Prod Chem

- Acute Tox/PL

- Tox CAS

- Efb

- CPP



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

May 15, 2012

MEMORANDUM

Subject: Name of Pesticide Product: EFFIPRO® PLUS TOPICAL SOLUTION FOR DOGS
EPA Reg. No. /File Symbol: 2382-RIO
DP Barcode: DP 398341
Decision No.: 459013
Action Code: R310
PC Codes: 129032 (Pyriproxyfen: 2.9%)
129121 (Fipronil: 9.7%)

From: Byron T. Backus, Ph.D., Toxicologist
Technical Review Branch
Registration Division (7505P)

Byron T. Backus
May 15, 2012

M. Hashim - Team Leader
5-15-12 /Tox

To: Bonaventure Akinlosotu/Richard Gebken RM 10
Insecticide Branch
Registration Division (7505P)

Registrant: VIRBAC AH, INC.

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>by wt.</u>
129121 Fipronil	9.7%
129032 Pyriproxyfen	2.9%
<u>Other Ingredient(s):</u>	<u>87.4%</u>
TOTAL	100.0%

ACTION REQUESTED: The Risk Manager requests:

"For your review: R310. MRID 486969-10 to -14; for a Fipronil + Pyriproxyfen containing Spot-On for dogs. Submits prod chem., tox, efficacy and CAS data..."

BACKGROUND:

The material received for review includes a proposed label, indicating the product is packaged in single-use applicators (1, 3, 6 or 36 applicators per package). Dosage rates are stated to be 0.023 fl. oz. (0.67 mL) "for small dogs and puppies 8 weeks old or older and up to 22.9 lbs," 0.045 fl. oz. (1.34 mL) for dogs weighing 23-44.9 lbs, 0.091 fl. oz. (2.68 mL) for dogs weighing 45-88.9 lbs, and 0.136 fl. oz. (4.02 mL) for dogs weighing 89-132 lbs. The product is to be applied no more frequently than once a month ("Effective monthly control of fleas and ticks," and "Once monthly application." There are five acute toxicity studies (MRID 48696910, acute oral toxicity study in rats; 48696911, acute dermal toxicity study in rats; 48696912, acute eye irritation study in rabbits; 48696913, acute dermal irritation study in rabbits; and 48696914, contact hypersensitivity in albino guinea pigs, Buehler test), and a waiver request for the inhalation toxicity study requirement. In addition, there is a basic CSF, dated October 21, 2011.

COMMENTS AND RECOMMENDATIONS:

1. The acute toxicity studies in MRIDs 48696910-48696914 were reviewed by a contractor, Summetic. The resulting DER was reviewed by TRB, and the appropriate revisions, if necessary, were made. It is concluded that these five acute toxicity studies are acceptable, and can be used to support the registration of 2382-RIO.
2. TRB has reviewed the acute inhalation toxicity study waiver request, and concludes that, based on the proposed product use and minimal potential inhalation exposure, this study can be waived and the product can be assigned to Toxicity Category IV by the inhalation exposure route.
3. Based on the results of the acute toxicity studies, the following is the acute toxicity profile for 2382-RIO (EFFIPRO® PLUS TOPICAL SOLUTION FOR DOGS):

Acute oral toxicity	III	Acceptable	MRID 48696910
Acute dermal toxicity	III	Acceptable	MRID 48696911
Acute inhalation toxicity	IV	Waived	n/a
Primary eye irritation	III	Acceptable	MRID 48696912
Primary dermal irritation	IV	Acceptable	MRID 48696913
Dermal sensitization	Negative	Acceptable	MRID 48696914

4. Based on the acute toxicity profile above, the following is the precautionary and first aid labeling for 2382-RIO, as obtained from the TRB Label Review System.

PRODUCT ID #: 002382-00189

PRODUCT NAME: EFFIPRO® PLUS TOPICAL SOLUTION FOR DOGS

PRECAUTIONARY STATEMENTS

SIGNAL WORD: CAUTION

Hazards to Humans and Domestic Animals:

Harmful if absorbed through skin. Harmful if swallowed. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking,

chewing gum, using tobacco or using the toilet. Wear long-sleeved shirt and long pants, socks, shoes, and gloves. Remove and wash contaminated clothing before reuse. [Wear protective eyewear.]*

*[Protective eyewear may be specified, if appropriate].

First Aid:

If on skin:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

If swallowed:

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything to an unconscious person.

If in eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- Call a poison control center or doctor for treatment advice.

NOTE TO PHYSICIAN: Note to PM/CRM/Registrant: The proposed label should contain a "Note to Physician". The following statements are suggested types of information that may be included, if applicable: - technical information on symptomatology; - use of supportive treatments to maintain life functions; - medicine that will counteract the specific physiological effects of the pesticide; - company telephone number to specific medical personnel who can provide specialized medical advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

5. The basic CSF dated October 21, 2011 for 2382-RIO should be reviewed and accepted by the TRB Chemistry Team.

DATA EVALUATION RECORD

PYRIPROXYFEN AND FIPRONIL

[104.11; EFFIPRO[®] PLUS TOPICAL SOLUTION FOR DOGS]

**STUDY TYPE: ACUTE ORAL TOXICITY - RAT [OCSP 870.1100; OECD 425]
ACUTE DERMAL TOXICITY - RAT [OCSP 870.1200; OECD 402]
ACUTE EYE IRRITATION - RABBIT [OCSP 870.2400; OECD 405]
ACUTE DERMAL IRRITATION - RABBIT [OCSP 870.2500; OECD 404]
DERMAL SENSITIZATION - GUINEA PIG [OCSP 870.2600; OECD 406]
MRID: 486969-10, 486969-11, 486969-12, 486969-13, and 486969-14**

Prepared for
Registration Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Prepared by
Summitec Corporation
9724 Kingston Pike, Suite 602
Knoxville, Tennessee 37922

Task Order No. 3-C-10

Primary Reviewer:
Donna L. Fefee, D.V.M.

Signature: Donna L. Fefee, NE
Date: APR 16 2012

Secondary Reviewers:
Thomas C. Marshall, Ph.D., D.A.B.T.

Signature: Thomas C. Marshall, AL
Date: APR 16 2012

Robert H. Ross, M.S., Program Manager

Signature: Robert H. Ross
Date: APR 16 2012

Quality Assurance:
Angela M. Edmonds, B.S.

Signature: Angela M. Edmonds
Date: APR 16 2012

Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

EPA Reviewer: Byron T. Backus, Ph.D.
Risk Manager (EPA): 10

Date: May 15, 2012

The following table is the Acute Toxicity Data Evaluation Record (DER) for the five studies submitted for the proposed product, File Symbol 2382-RIO

1. DP BARCODE: 398341				
2. PC CODES: 129032 and 129121				
3. CURRENT DATE: May 15, 2012				
4. TEST MATERIAL: 104.11; Batch #FMA 11123-1; 9.68% Fipronil and 2.98% Pyriproxyfen (per certificate of analysis); yellow odourless liquid (or colorless to yellowish liquid); density: 1.036 g/mL; pH: 4-5 (MRID 48696912); expiration date: November 2011; stored at room temperature				
Study/Species/Lab Study # /Date	MRID	Results	Tox Cat	Core Grade
Acute oral toxicity / rat Harlan Laboratories Ltd. (Itingen, Switzerland) Study #D34666 / November 18, 2011 OCSPP 870.1100; OECD 425	48696910	LD ₅₀ Females = 2000 mg/kg bw [95% PL Confidence interval is 0 to >20,000] Four tested (with dosing on day 1) in accordance with AOT425 StatPgm (assumed sigma=0.5): 1 at 550 mg/kg, 3 at 2000 mg/kg. 550 mg/kg: no deaths, abnormal clinical signs, bw effects, or gross findings. 2000 mg/kg: 2 deaths (days 6 & 9); clinical signs: ruffled fur and/or hunched posture in 2/3 (day 1); survivor lost wt days 1-8 but had net gain for the study overall; gross necropsy findings limited to lung congestion in both decedents. <i>Deviation from OECD 425: no rationale provided for use of starting dose different from default.</i>	III	A

Acute dermal toxicity / rat Harlan Laboratories Ltd. (Itingen, Switzerland) Study #D34677 / November 18, 2011 OCSPP 870.1200; OECD 402	48696911	LD ₅₀ > 2000 mg/kg (both sexes) No deaths, abnormal systemic clinical signs, or abnormal gross findings; BW affected: 4/5 males and 4/5 females lost weight during days 1-8, all animals gained during days 8-15 and most had net BW gain over days 1-15 (1 female had net loss over days 1-15); local effects: erythema on 1 male on day 2 (resolved by day 3), desquamation and/or focal crusts on 5/5 males and 4/5 females beginning days 2-6 (resolved by day 15 except desquamation in 1 male and 1 female). <i>Note: It is unclear whether the size of the dose site really was 10% of the body surface area (BSA). The study author stated that application sites were approximately 10% of body surface area, but it was also stated that application sites were covered by a gauze pad measuring ~25 cm², which, according to standard formulas, would be less than 10% of the BSA for rats in the BW range used in this study (193.7- 276.8).</i> <i>Deficiency: Systemic clinical signs data from days 2-15 were omitted from the study report.</i>	III	A
Acute inhalation toxicity / rat	n.a.	Waiver recommended on basis of product use (pet spot-on) and minimal inhalation exposure.	(IV)	W
Primary eye irritation / rabbit Harlan Laboratories Ltd. (Itingen, Switzerland) Study #D34688 / November 30, 2011 OCSPP 870.2400; OECD 405	48696912	Use of anesthetic not mentioned. No corneal or iridial effects seen in any eye at any time point. Conjunctival redness present in 3/3 eyes at 1 hr through 7 days and in 2/3 and 1/3 eyes at 10 and 14 days post instillation (score=1-2). Conjunctival discharge seen in 2 eyes at 1 hour (score=1) and not seen thereafter. Slight to moderate scleral reddening seen in 3 eyes at 1 hour and in 2 eyes at 24-72 hours. Conjunctivitis scored as "positive" in 2/3 eyes at 24-48 hrs and in 1/3	III	A

		eyes at 72 hours. MMTS=3.33, at 1-48 hours; Mildly irritating (per Kay and Calandra). Classified based on resolution of “positive” irritation within 7 days or less.		
Primary dermal irritation / rabbit Harlan Laboratories Ltd. (Itingen, Switzerland) Study #D34690 / November 30, 2011 OCSPP 870.2500; OECD 404	48696913	PDI at 72 hours=0.00 There were no observations of erythema, edema, or other changes to the skin on any animal at any time point. “Nonirritant” based on US EPA (1988).	IV	A
Dermal sensitization / guinea pig Harlan Laboratories Ltd. (Fullinsdorf, Switzerland) Study #D34701 / October 27, 2011 OCSPP 870.2600; OECD 406	48696914	Tested using Buehler method Induction used 100% concentration; challenge used 75% concentration in diethylene glycol monoethyl ether vehicle. No positive dermal reactions on treated or vehicle control animals following challenge. <i>Not a sensitizer</i> <i>Deficiencies: Justification not provided for usage of non-standard vehicle. It appears that in the positive control study the testing lab was not able to identify the HNIC; two challenge concentrations (neither of which was a HNIC) were selected, based, in part, upon historical results. Results of initial challenge were equivocal, and a re-challenge was necessary. “Correct” results were attained, but the laboratory has not necessarily demonstrated proficiency.</i>	--	A

Core Grade Key: A =Acceptable, S = Supplementary, U = Unacceptable, D = Data Gap, W =
Waived



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

FILE

BARCODE No.: 398340; FILE SYMBOL No.: 2382-RIO;
PRODUCT NAME: Effipro Plus Topical Solution for Dogs; DECISION No.: 459013;
PC Code(s): 129121 & 120932; Action Code: R310; FOOD Use: No

DATE: May 7, 2012

SUBJECT: Product Name: **Effipro Plus Topical Solution for Dogs**

FROM: Akiva Abramovitch, Ph.D.
Technical Review Branch / RD (7505P)

THROUGH: Shyam Mathur, Ph.D.
Product Chemistry Team Leader
Technical Review Branch/RD (7505P)

TO: Bonaventure Akinlosotu/Richard Gebken, PM 10
Insecticide Branch/ RD (7505C)

Company Name: Virbac
Formulation Type: Spot-On Solution

INTRODUCTION:

The applicant has submitted an application for registration of a new end use product. In support of the registration application, the registrant has submitted product chemistry data corresponding to guideline 830 series, group A & group B (MRIDs 486969-01 through -09). The CSF of the basic formulation (dated 10/21/2011) was submitted along with the product label. TRB has been asked to determine the acceptability of the product chemistry data and the proposed basic CSF dated October 21, 2011.

SUMMARY OF FINDINGS:

1. Name of Active Ingredient: Fipronil (9.7%) and Pyriproxyfen (2.9%).
2. Has the registrant claimed substantial similarity to a registered product?

[] Yes; [X] No; [] NA; if yes give the registration number of the cited product.

3. All the source materials for the active ingredients are derived from the registered sources:

[X] Yes; [] No. [REDACTED] added to the CSF.

BARCODE No.: 398340;

FILE SYMBOL No.: 2382-RIO;

PRODUCT NAME: Effipro Plus Topical Solution for Dogs; **DECISION No.:** 459013;

PC Code(s): 129121& 120932; **Action Code:** R310;

FOOD Use: No

4. All inert ingredients have been screened by IIAB (and found to be approved for the proposed labeled uses: ☒ Yes; ☐ No.

5. Confidential Statement of Formula(s):

☒ Basic Dated: October 21, 2011;

6. Product label

a. Ingredient statement: Nominal concentration of AI listed on CSF(s) concur with product label (PR Notice 91-2).

☒ Yes, if not, explain below:

Is the sub statement in compliance with PR Notice 97-6 (inert ingredient vs other ingredient)?

☒ Yes; ☐ No; if not, explain below:

Metallic equivalent: ☐ Yes ☒ NA;

Soluble arsenic: ☐ Yes ☒ NA

Isomeric ratios: ☐ Yes ☒ NA

Acid equivalent: ☐ Yes ☒ NA; {name} acid equivalent = xx %

b. Health related sub statements: Product contains?

Petroleum distillate at > 10%: ☐ Yes ☒ No ☐ NA

Methanol at > 4%: ☐ Yes ☒ No ☐ NA

Sodium nitrate/Sodium nitrite ☐ Yes ☒ No ☐ NA

c. Physical chemical hazard statement: Product label requires a statement per 40 CFR §156.78 for: flammability, explosive potential or electric insulator breakdown?

☐ Yes ☒ No

Is the sub statement in compliance with PR Notice 98-6 (Total Release Fogger)?

☐ Yes, ☐ No, ☒ NA, if not, explain below:

d. Label requires an additional Storage and Disposal statement:

☐ Yes ☒ No

BARCODE No.: 398340;

FILE SYMBOL No.: 2382-RIO;

PRODUCT NAME: Effipro Plus Topical Solution for Dogs; **DECISION No.:** 459013;

PC Code(s): 129121& 120932; **Action Code:** R310;

FOOD Use: No

7. Group A: Product Chemistry Data

TRB's determination of the acceptability for the proposed product is listed in the tables below.

Guideline No.	Study Title		Data submitted		TRB's Assessment of Data	MRID Nos.
			Yes	No		
830.1550	Product Identity & Composition		X		A	486969-01
830.1600	Description of materials used to produce the product		X		A	486969-01
830.1650	Description of formulation process		X		A	486969-01
830.1670	Discussion on the formation of impurities		X		A	486969-01
830.1700	Preliminary analysis		X		A	486969-08 and -09
830.1750	Certified limits (158.350)	Standard certified Limits	X		A	486969-01
		Proposed Limits			NA	
		Justification for wider limits			NA	
830.1800	Enforcement analytical method		X		A (HPLC method)	486969-08 and -09

A = Acceptance, N = Not Acceptable, G = Data Gap, W = Waiver Request, I = In Progress, NA = Not Applicable; U = Upgradeable

BARCODE No.: 398340;

FILE SYMBOL No.: 2382-RIO;

PRODUCT NAME: Effipro Plus Topical Solution for Dogs; **DECISION No.:** 459013;

PC Code(s): 129121& 120932; **Action Code:** R310;

FOOD Use: No

8. Group B:

Guideline No.	Study Title	Value or Qualitative Description	TRB's Assessment of Data	MRID Nos.
830.6303	Physical State	Colorless liquid with sweet odor	A	486969-02
830.6315	Flammability	94.3°C flashpoint	A	486969-04
830.6316	Explosibility	NA, not considered to be potentially explosive	A	486969-02
830.7000	pH	5.95 1% solution at 23 C	A	486969-05
830.7300	Density (units)	1.032 g/cm ³	A	486969-07

A = Acceptance, N = Not Acceptable, G = Data Gap, W = Waiver request,
NA = Not applicable, I = In progress, U = Upgradeable

CONCLUSIONS:

TRB has reviewed the CSF(s) and product chemistry data for the proposed end use product and has concluded:

1. The proposed CSF for the basic formulation dated October 21 2011 is acceptable
2. The data submitted corresponding to guidelines 830.1550 (product identity and composition), 830.1600 (description of materials used to produce the product) , 830.1650 (description of formulation process), 830.1670 (discussion on the formation of impurity), 830.1750 (certified limits), and 830.1800 (enforcement analytical method) are acceptable.
3. The product chemistry data submitted corresponding to guidelines 830.6302 (color), 830.6303 (physical state), 830.6304 (odor), 830.6314 (oxidation/reduction), 830.6315 (flammability), 830.6316 (explosibility), 830.7000 (pH), 830.7100 (viscosity), and 830.7300 (density) are acceptable.
4. The storage stability (guideline 830.6317) and corrosion characteristics (guideline 830.6320) studies were not submitted. These physical/chemical properties are required and it is recommended that observations should be made at 0, 3, 6, 9, and 12 month intervals.
5. The proposed label was screened as it pertains to the product chemistry requirements. The review of the proposed label and uses are the purview of the RM team.



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WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

June 7, 2012

MEMORANDUM

Subject: Name of Pesticide Product: EFFIPRO® PLUS TOPICAL SOLUTION FOR DOGS
EPA Reg. No. /File Symbol: 2382-RIO
DP Barcode: DP 398344
Decision No.: 459013
Action Code: R310
PC Codes: 129032 (Pyriproxyfen: 2.9%)
129121 (Fipronil: 9.7%)

From: Byron T. Backus, Ph.D., Toxicologist
Technical Review Branch
Registration Division (7505P)

Byron T. Backus
June 7, 2012

W. Haslam
Team leader Toxicology

To: Bonaventure Akinlosotu/Richard Gebken RM 10
Insecticide Branch
Registration Division (7505P)

Registrant: VIRBAC AH, INC.

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>by wt.</u>
129121 Fipronil	9.7%
129032 Pyriproxyfen	2.9%
<u>Other Ingredient(s):</u>	<u>87.4%</u>
TOTAL	100.0%

ACTION REQUESTED: The Risk Manager requests:

“For your review: R310. MRID 48696916; for a Fipronil + Pyriproxyfen containing Spot-On for dogs. Submits prod chem., tox, efficacy and CAS data...”

BACKGROUND:

The material received for review includes a proposed label, indicating the product is packaged in single-use applicators (1, 3, 6 or 36 applicators per package). Dosage rates are stated to be 0.023 fl. oz. (0.67 mL) “for small dogs and puppies 8 weeks old or older and up to 22.9 lbs,” 0.045 fl. oz. (1.34 mL) for dogs weighing 23-44.9 lbs, 0.091 fl. oz. (2.68 mL) for dogs weighing 45-88.9 lbs, and 0.136 fl. oz. (4.02 mL) for dogs weighing 89-132 lbs. The product is to be applied no more frequently than once a month (“Effective monthly control of fleas and ticks,” and “Once monthly application.” There is a data matrix (dated December 20, 2011) which cites 12 studies to satisfy the companion animal safety data requirement (MRIDs 43444905, 43577711, 43863802, 43121110, 43121111, 45620507, 43396408, 43612601, 44900902, 44900903, 42178309, and “new submission” [presumably the material in MRID 48696916, which consists of summaries of several previously reviewed companion animal safety and other studies; OPPIN indicates no studies have been submitted for 2382-RIO] from Virbac.

COMMENTS AND RECOMMENDATIONS:

1. The following are review summaries of the eleven studies (the 12 indicated above less the material in MRID 48696916) that have been cited to satisfy the 870.7200 data requirement to support the registration of 2382-RIO.
 - MRID 43444905: Schwartz, E. (1994) Domestic Animal Safety Study of RM1601C Topical Spray (Frontline Spray Treatment) in Juvenile Dogs: Lab Project Number: 94423: PS-232DAS. Unpublished study prepared by White Eagle Toxicology Labs. 171 p. [according to OPPIN the products supported by this study are 65331-1 and 65331-EUP-1; DERs for this study are in TXRs 0011677 and 0011764; Groups of 4 or 6 beagles (~8 weeks old) per sex received single applications of RM 1601C Topical Spray [0.25% w/v fipronil = 0.29% w/w fipronil] at dosages of 6 mL/kg (1X recommended dose) or 30 mL/kg (5X). A control group of 4/sex was treated with the vehicle at 30 mL/kg. This study was upgraded to acceptable in TXR 0011764].
 - MRID 43577711: Walker, K. (1995) Discussion in Support of Bridging Domestic Animal Safety Data on Frontline Spray Treatment to Frontline Spot Treatment Data Package. Unpublished study prepared by Rhone Merieux, Inc. 6 p. [According to OPPIN the product supported is 65331-EUP-E; this is not an actual study, but an argument as to why there is justification for linking the spot-on product containing ~10% fipronil to the data base of an existing product (Frontline® Spray Treatment, 0.25% w/v fipronil)].
 - MRID 43863802: Powell, L.; Paffett, R. (1995) Domestic Animal Safety Study by Topical Administration to Dogs: Fipronil Spot Treatment (RM 1601E): Lab Project Number: MRX 23/950406. Unpublished study prepared by Huntingdon Research Centre, Ltd. 219 p. [According to OPPIN the product supported was 65331-EUP-E; from TXR 0051187: “...4 male and 4 female pure-bred beagle dogs (approximately 10 weeks of age) were administered a single topical treatment of RM1601E/62 (9.7% fipronil) at either 1X, 3X or 5X the recommended dose (0.133 mg/kg/spot) once every month for a total of 6 treatments... 4 male and 4 female dogs served as a control group and were treated with the formulation vehicle at 5X the recommended dosage. A similar group served as an untreated control... The study demonstrated that RM1601E/62 (9.7% fipronil) has at least a 5X margin of safety

in dogs greater than 10 weeks of age. The product label should state that there may be temporary irritation after application.” The study was classified as acceptable].

- MRID 43121110: Arnaud, J.; Consalvi, P. (1993) Assessment of Tolerance of a 0.25% RM 1601 Spray Formulation in Dogs at 3, 9, and 15 mL/kg When Applied 6 times to the Haircoat at 28 Day Intervals: Revised: Lab Project Number CLI138. Unpublished study prepared by Rhone Merieux, Inc. 69 p. [according to OPPIN the product supported by this study is 65331-EUP-1; a DER for this study is in TXR 0010923; groups of 3M & 3F beagle dogs were topically administered 6 treatments of 0.25% fipronil at dosages of either 0, 3, 9 or 15 mL/kg (0, 7.5, 22.5 and 37.5 mg fipronil/kg, respectively) at 28-day intervals. The proposed recommended dose for the 0.25% product was 3 to 6 mL/kg; 0.67 mL of a 9.7% fipronil product applied to a 5 kg dog would be equivalent to a dosage of 13 mg fipronil/kg. From TXR 0010923: “Classification: Unacceptable because: 1) the highest dosage level was not 5X the highest recommended dose; and 2) the study was not conducted in compliance with the GLP regulations].
- MRID 43121111: Arnaud, J.; Consalvi, P. (1993) Domestic Animal Safety: Assessment of the Tolerance of a 0.25% RM 1601 Spray in Nursing Puppies Administered Twice at a 28 Day Interval at a Dose Rate of 6 mL/kg: Revised: Lab Project Number CLI 180. Unpublished study prepared by Rhone Merieux, Inc. 32 p. [According to OPPIN the product supported by this study is 65331-EUP-1; a DER for this study is in TXR 0010923; a total of 27 male and 21 female nursing puppies (9 litters of either beagle, spaniel or griffon breeds) topically received two treatments of 0.25% formulation at a dosage of 6 mL/kg (proposed recommended dosage = 6 mL/kg) with 28 days between the treatments. The dams of the litters were treated at the same dosage. Twenty-six male and 15 females served as untreated controls. Six treated puppies, including four from the same spaniel litter, died before weaning and another died after weaning. Parvovirus was isolated from the spaniel litter. One control puppy died; there was no statistical difference in mortality between the groups. Growth rates were either comparable to or exceeded the applicable control group for the beagle and griffon breeds, but were lower for the spaniel (this lower growth rate may have been from the parvovirus infection). Classification: Unacceptable because: 1) the study was conducted with nursing rather than weaned puppies; 2) the highest dosage level was not at 5X the recommended dose; 3) the study was not conducted in compliance with GLP regulations].
- MRID 45620507: Godin, C.; Alva, R. (2000) ML-2,095,988 509T/Dog/Solution/Topical/Safety/Tolerance/Reproduction, Reactions: Final Report: Lab Project Number: PR&D 0020201: WEL 99885: PR&D 00202. Unpublished study prepared by White Eagle Toxicology Laboratory. 123 p. [From OPPIN the product supported by this study is 65331-5; the review of this study is in TXR 5008387: In a special (reproductive) companion animal safety study a topical formulation containing 10% w/v fipronil and 9% w/v (S)-methoprene was administered at 0X (Group 1; sham-treated controls), 1X or 0.133 mL/kg (Group 2) and 3X or 0.399 mL/kg (Group 3) to groups of 12 adult female beagle dogs (bitches) prior to and during pregnancy, through parturition and to weaning of the puppies. The only dose-related effects observed in bitches were pink skin at the application site on days of treatment (recorded 15 times in Group 2, 37 times in Group 3), and pink skin at the application site on the day following treatment (3 times in Group 3). There was no indication of an adverse effect on any reproductive parameters (including gestation index, incidence of cesarean section, incidences of stillborn pups, incidences of pups dying between birth and weaning). There were no significant differences between puppies from the 3 groups with respect to physiological parameters (mean body

weights, mean rectal temperatures, mean respiratory rates, mean heart rates) measured on post-parturition days 14, 28 and 42 .

Although no dogs were dosed at 5X level, and no blood was taken for clinical chemistry and hematology measurements, the purpose of this study was to allow a label claim on breeding, pregnant and lactating bitches. TRB has previously reviewed a companion animal (dog) study for this formulation which included a 5X dosage group and measurements of clinical chemistry and hematology parameters. This study is classified as acceptable. The findings of this study are adequate to support the use of EPA Reg. Nos. 65331-3 and 65331-5 at the specified label use rates (varying according to the weight of dog) at 28-day intervals on breeding, pregnant and lactating bitches].

- MRID 43396408: Pennington, R.; Clymer, B. (1994) Study Report for the Target Animal Safety Evaluation of ECTO Flea and Tick Insecticide with IGR on Dogs: Lab Project Number: A-94-01-F701-007: 278-94-59: F701R09. Unpublished study prepared by CALV, Inc. & CRC. 28 p. [From OPPIN the product supported by this study is 67505-3; the review of this study is in TXR 0011565: 4 groups of mixed breed/beagle adults and puppies were exposed to 0, vehicle control (at 5X) or a formulation containing 45% permethrin and 5% pyriproxyfen at weekly intervals for a total of two applications. At 1X and above, slight to severe dermal reactions were observed. In the vehicle treated group 5/6 animals exhibited mild to severe dermal reactions which were as severe as in the 5X treated group. The study did not demonstrate a 3-5 fold safety factor between use as directed and dermal reactions].
- MRID 43612601: Pennington, R.; Kuhn, J. (1995) Report for the Target Animal Safety Evaluation of ECTO Flea and Tick Insecticide with IGR on Dogs: Lab Project Number: A-93-01-F701-027: 1617-94: F701R14. Unpublished study prepared by Ecto Development Corp. and Stillmeadow, Inc. 24 p. [From OPPIN the product supported by this study is 67505-3; the review of this study is in TXR 0011865: Adult dogs and puppies (1-2 subjects, ~3 months) 6/dose group were dosed once as control (untreated), 1X and 5X the label dosage rate of Ecto Flea and Tick Insecticide with IGR and followed for 31 days. No reactions to treatment were noted. The study demonstrated a 5X safety factor between use as directed and a dose level not resulting in toxicity or irritation. The study is classified as acceptable to support the use of this product (EPA Reg. No. 67505-3) on adult dogs (>6 months of age) only].
- MRID 44900902: Fabreguettes, C. (1998) Tolerance in 3 Month Old Puppies: Pyriproxyfen 2% Spot On For Dogs: Lab Project Number: CIT 15615TSC. Unpublished study prepared by Centre International de Toxicologie. 253 p. [From OPPIN the product supported by this study is 2382-RTU; Pyriproxyfen (2%) was topically applied to groups of three male and three female beagle dogs (3 months old; mean body weight of males 4.4 kg; females 3.9 kg) for two periods of three consecutive days each (days 1, 2, and 3 and then days 19, 20 and 21) at 0.6 mL (1X), 1.2 mL (2X), and 1.8 mL (3X) of the recommended therapeutic dose level, followed by a 15-day observation period. Controls were treated with 1.8 mL of excipient. No animals died during the study and there were no treatment related clinical signs. No changes in body weight, food consumption, water consumption, hematology, clinical chemistry, or urinalysis were treatment related. Electrocardiographic and ophthalmological examinations did not reveal any abnormalities in the treated animals. Microscopic examination did not reveal any treatment-related effects. Classification: Unacceptable; Deviations include not testing six animals/sex/group, and not testing at a dose of 5X].

- MRID 44900903: Fabreguettes, C. (1999) Tolerance in 1 Month Old Puppies: Pyriproxyfen 2% Spot On For Dogs: Lab Project Number: CIT 15644TSC. Unpublished study prepared by Centre International de Toxicologie. 194 p. [From OPPIN the product supported by this study is 2382-RTU; Pyriproxyfen 2% was topically applied to groups of three male and three female beagle dogs (1 month old) for two periods of three consecutive days (days 1, 2, and 3 and then days 19, 20 and 21) at 0.6 mL (1X) and 1.8 mL (3X) of the recommended therapeutic dose level, followed by a 15-day observation period. Controls were treated with 1.8 mL of excipient. No animals died during the study and there were no treatment related clinical signs. Body weight gain was slightly reduced in treated animals, but not to statistically significant levels. Changes in hematology and clinical chemistry parameters were sporadic and did not appear to be related to treatment. Electrocardiographic and ophthalmological examinations revealed no abnormalities in the treated animals. Macroscopic and microscopic examination revealed no treatment related changes, although serous contents were observed in the abdominal cavity in 1/6 animals in the low dose group and 4/6 animals in the high dose group (but not in any control animals). The product labeling indicates that the dose is 0.021 fl. oz or 0.6 mL, and the application instructions state that the product should be reapplied every three months and should not be applied to puppies less than 1 month old. In this study the product was applied at 1X and 3X dose levels once per day for three consecutive days and again for another 3-day period 19-21 days after the first treatment. Classification: Unacceptable; Deviations include not testing six animals/sex/group, and not testing at a dose of 5X].
 - MRID 42178309: Chapman, E. (1991) S31183: Toxicity Study by Oral (Capsule) Administration to Beagle Dogs for 52 Weeks (Sumilarv Technical Grade): Lab Project Number: 91/0776. Unpublished study prepared by Life Science Research Ltd. 320 p. [Dose levels tested: 0, 30, 100, 300 and 1000 mg/kg/day in the diet for 54 weeks; study demonstrates a low level of toxicity associated with chronic exposure to Pyriproxyfen; the dietary NOEL was 100 mg/kg/day].
2. After comparing the CSFs for 2382-RIO and 65331-3, TRB concludes that the studies cited by the registrant to satisfy the 870.7200 data requirements adequately support the use of 2382-RIO at the indicated dosage rates (0.023 fl. oz. or 0.67 mL on dogs up to 22.9 lbs; 0.045 fl. oz. or 1.34 mL on dogs 23-44.9 lbs; 0.091 fl. oz. or 2.68 mL on dogs 45-88.9 lbs; 0.136 fl. oz. or 4.02 mL on dogs 89-132 lbs) on adult dogs and puppies of 8 weeks of age and older on a once-a-month (or every 4 weeks) basis.
 3. TRB also concludes that because of the presence of 2.9% pyriproxyfen in 2382-RIO the study in MRID 45620507 cannot be used to support the use of 2382-RIO on breeding, pregnant and/or lactating bitches [although this claim does not appear on the proposed label dated December 14, 2011]. Labeling must then also include the statement: "Consult a veterinarian before using this product on debilitated, aged, pregnant or nursing animals" as indicated in PR Notice 96-6.



48696900

December 20, 2011

Richard Gebken, PM 10
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Document Processing Desk (REGFEE)
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Subject: EFFIPRO[®] PLUS Topical Solution for Dogs (EPA File Symbol 2382-²¹⁰TBA);
New Product Application.

Dear Mr. Gebken,

Virbac Animal Health (Virbac AH, Inc. P. O. Box 162059, Ft. Worth, TX 76137, (Company Number 2382)) is hereby submitting an application to register the spot-on pesticide product EFFIPRO[®] PLUS Topical Solution for Dogs.

This product contains the active ingredients fipronil and pyriproxifen and is intended to control fleas, ticks, mosquitoes, and other pests on dogs only.

Pyriproxifen itself is registered alone and in combination with other active ingredients in numerous end use products for spot-on insect growth regulator use on dogs.

As indicated on Form 8570-34, Virbac is using the selective method to address applicable data requirements for this application pursuant to 40 CFR 152.90. Pursuant to 40 CFR 152.93, Offer to Pay letters are being sent to the submitters of data cited in Virbac's application that were originally submitted within the past 15 years.

Below is a list of the components included with this application:

1. Cover Letter;
2. Transmittal Document;
3. Application for Pesticide Form 8570-1;
4. Confidential Statement of Formula-2 Copies;
5. Data Matrix Form 8570-4; (EUP and TGA1);
6. Certification of Data Citation Form 8570-34;
7. Proposed Label - 5 copies;
8. 3 copies of bound PR 86-5 compliant study reports supporting registration;
9. Waiver Request for Acute Inhalation Study (attached to Cover Letter);
10. Letter of Self-certification of Child-Resistant Packaging;
11. Formulator's Exemption Form 8570-27; and
12. Copy of PRIA Check for category R-310 (\$4807).

Child-Resistant Packaging

EFFIPRO® PLUS Topical Solution for Dogs and will be marketed in single dose unit applicators in packages of 1, 3, 6, and 36. These single dose applicators for the 0.67 ml, 1.34 ml, 2.68 ml, and 4.02 ml dose sizes have been previously tested, and CRP certification has been accepted by EPA. All relevant test data supporting self-certification have been reviewed and are cited in the attached Data Matrix. A self-certification letter is also attached.

PRIA Considerations

After reviewing the Agency's PRIA category interpretations, we believe that the R-310 PRIA category and a 6 month review period is appropriate for this product. Consequently, please find a copy of one previously submitted check in the amount of \$4807 to cover the PRIA fee.

Should you have any questions about this application package, please do not hesitate to contact me via telephone at 682-647-3576 or via e-mail at craig.parks@virbacus.com.

Sincerely,



Craig Parks, MS, DVM
Vice President, Research & Development
Virbac Animal Health, Inc.

Attachments

Virbac Effipro PLUS DOG
12/20/2011

TRANSMITTAL DOCUMENT

NAME AND ADDRESS OF SUBMITTER:

Virbac, Inc. (EPA Company Number 2382)
P.O. Box 162059
Fort Worth, TX 76161

REGULATORY ACTION SUPPORTED BY THIS PACKAGE:

This submission is an application to register an end use pro namely EFFIPRO[®] PLUS Topical Solution for Dogs. Effipro[®] EFFIPRO[®] PLUS Topical Solution for Dogs contains the active ingredients Fipronil and Pyriproxyfen.

SUBMITTAL DATE:

December 20, 2011

Volume	Study Title	MRID No.
1	Administrative Materials Effipro [®] Plus Topical Solution for Dogs	
	<i>Group A Product Chemistry</i>	
2	OPPTS 830.1550, 830.1750, 830.1600, 830.1620, 830.1650, 830.1670 EFFIPRO [®] PLUS Topical Solution for Dogs	48696901
	<i>Group B Product Chemistry</i>	
3	OPPTS 830.6302, 830.6303, 830.6304 Determination of the Physico-Chemical Property "Appearance (Color, Physical State and Odor)"	48696902
4	OPPTS 830.6314 Determination of Oxidation / Reduction (Chemical Incompatibility)	48696903
5	OPPTS 830.6315 Determination of the Physico-Chemical Property "Flash Point"	48696904
6	OPPTS 830.7000 Determination of the Physico-Chemical Property "pH"	48696905
7	OPPTS 830.7100 Determination of Physico-Chemical Property "Viscosity"	48696906
8	OPPTS 830.7300 Determination of the Physico-Chemical Property "Relative Density"	48696907

Volume	Study Title	MRID No.
9	OPPTS 830.1700, 830.1800 Quantification of the Active Ingredients Fipronil and Pyriproxyfen in Five Batches by Validated Methods	48696908
10	OPPTS 830.1800 Enforcement Analytical Method – Quantification of the Active Ingredients Fipronil and Pyriproxyfen	48696909
	<i>Acute Toxicity</i>	
11	OPPTS 870.1100 Acute Oral Toxicity Study in Rats – Up-and-Down-Procedure	48696910
12	OPPTS 870.1200 Acute Dermal Toxicity Study in Rats	48696911
13	OPPTS 870.2400 Acute Eye Irritation Study in Rabbits	48696912
14	OPPTS 870.2500 Acute Dermal Irritation Study in Rabbits	48696913
15	OPPTS 870.2600 Contact Hypersensitivity in Albino Guinea Pigs, Buehler Test	48696914
	<i>Product Performance</i>	
16	OPPTS 810.3300 Summary of Efficacy Data for EFFIPRO® PLUS Topical Solution for Dogs	48696915
	<i>Product Safety</i>	
17	OPPTS 870.7200 Summary of Companion Animal Safety Data for EFFIPRO® PLUS Topical Solution for Dogs	48696916

DATA PACKAGE BEAN SHEET

Date: 02-Feb-2012

Page 1 of 2

Decision #: 459013

DP #: (398342)

PRIA

Parent DP #:

Submission #: 908748

E-Sub #:

*** Registration Information ***

Registration: 2382-RIO - EFFIPRO PLUS TOPICAL SOLUTION FOR DOGS

Company: 2382 - VIRBAC AH, INC.

Risk Manager: RM 10 - Richard Gebken - (703) 305-6701 Room# PY1 S-7237

Risk Manager Reviewer: Bonaventure Akinlosotu BAKINLOS

Sent Date: _____

Calculated Due Date: 10-Jul-2012

Edited Due Date: _____

Type of Registration: Product Registration - Section 3

Action Desc: (R310) NEW PRODUCT;NON-FAST TRACK (INCLUDES REVIEWS OF PRODUCT CHEMIST

Ingredients: 129032, Pyriproxyfen(2.9%)

129121, Fipronil(9.7%)

*** Data Package Information ***

Expedite: ☐ Yes ☒ No

Date Sent: 02-Feb-2012

Due Back: _____

DP Ingredient: 129032, Pyriproxyfen

129121, Fipronil

DP Title: efficacy

CSF Included: ☒ Yes ☐ No

Label Included: ☒ Yes ☐ No

Parent DP #: _____

Assigned To

Date In

Date Out

Organization: RD / IB

Last Possible Science Due Date: 10-Jun-2012

Team Name: Efficacy (IB)

Science Due Date: _____

Reviewer Name: _____

Sub Data Package Due Date: _____

Contractor Name: _____

*** Studies Sent for Review ***

Printed on Page 2

*** Additional Data Package for this Decision ***

Can be printed on its own page

*** Data Package Instructions ***

For your review: R310

MRID 48696915; for a Fipronil + Pyriproxyfen containing Spot-On for dogs.

Submits prod chem, tox, efficacy and CAS data; Cites CRP data.

Thanks, B.A

MRID	MRID Status	Citation Reference	Guideline	MRID Status
48696915		Villard, I. (2011) Summary of Efficacy Data for Effipro Plus Topical Solution for Dogs (Fipronil 9.7% and Pyriproxyfen 2.9% End Use Product). Project Number: VIRBAC/104/11/2. Unpublished study prepared by Isa Vet Biosciences 12p.	810.3300/Treatments to control pests of humans and pets	Pass (10-Jan-2012)



48696900

December 20, 2011

Richard Gebken, PM 10
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Document Processing Desk (REGFEE)
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Subject: EFFIPRO® PLUS Topical Solution for Dogs (EPA File Symbol 2382-TBA);
New Product Application.

Dear Mr. Gebken,

Virbac Animal Health (Virbac AH, Inc. P. O. Box 162059, Ft. Worth, TX 76137, (Company Number 2382)) is hereby submitting an application to register the spot-on pesticide product EFFIPRO® PLUS Topical Solution for Dogs.

This product contains the active ingredients fipronil and pyriproxifen and is intended to control fleas, ticks, mosquitoes, and other pests on dogs only.

Pyriproxifen itself is registered alone and in combination with other active ingredients in numerous end use products for spot-on insect growth regulator use on dogs.

As indicated on Form 8570-34, Virbac is using the selective method to address applicable data requirements for this application pursuant to 40 CFR 152.90. Pursuant to 40 CFR 152.93, Offer to Pay letters are being sent to the submitters of data cited in Virbac's application that were originally submitted within the past 15 years.

Below is a list of the components included with this application:

1. Cover Letter;
2. Transmittal Document;
3. Application for Pesticide Form 8570-1;
4. Confidential Statement of Formula-2 Copies;
5. Data Matrix Form 8570-4; (EUP and TGA1);
6. Certification of Data Citation Form 8570-34;
7. Proposed Label - 5 copies;
8. 3 copies of bound PR 86-5 compliant study reports supporting registration;
9. Waiver Request for Acute Inhalation Study (attached to Cover Letter);
10. Letter of Self-certification of Child-Resistant Packaging;
11. Formulator's Exemption Form 8570-27; and
12. Copy of PRIA Check for category R-310 (\$4807).

Child-Resistant Packaging

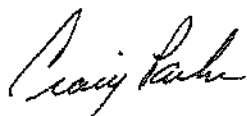
EFFIPRO® PLUS Topical Solution for Dogs and will be marketed in single dose unit applicators in packages of 1, 3, 6, and 36. These single dose applicators for the 0.67 ml, 1.34 ml, 2.68 ml, and 4.02 ml dose sizes have been previously tested, and CRP certification has been accepted by EPA. All relevant test data supporting self-certification have been reviewed and are cited in the attached Data Matrix. A self-certification letter is also attached.

PRIA Considerations

After reviewing the Agency's PRIA category interpretations, we believe that the R-310 PRIA category and a 6 month review period is appropriate for this product. Consequently, please find a copy of one previously submitted check in the amount of \$4807 to cover the PRIA fee.

Should you have any questions about this application package, please do not hesitate to contact me via telephone at 682-647-3576 or via e-mail at craig.parks@virbacus.com.

Sincerely,



Craig Parks, MS, DVM
Vice President, Research & Development
Virbac Animal Health, Inc.

Attachments

Virbac Effipro PLUS DOG
12/20/2011

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NAME AND ADDRESS OF SUBMITTER:

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SUBMITTAL DATE:

December 20, 2011

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5	OPPTS 830.6315 Determination of the Physico-Chemical Property "Flash Point"	48696904
6	OPPTS 830.7000 Determination of the Physico-Chemical Property "pH"	48696905
7	OPPTS 830.7100 Determination of Physico-Chemical Property "Viscosity"	48696906
8	OPPTS 830.7300 Determination of the Physico-Chemical Property "Relative Density"	48696907

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11	OPPTS 870.1100 Acute Oral Toxicity Study in Rats – Up-and-Down-Procedure	48696910
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	<i>Product Safety</i>	
17	OPPTS 870.7200 Summary of Companion Animal Safety Data for EFFIPRO® PLUS Topical Solution for Dogs	48696916

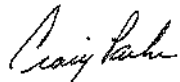
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

Date: December 20, 2011			EPA Reg. No./File Symbol 2382-TBA		Page 1 of 9
Applicant's/Registrant's Name & Address Virbac AH, Inc. PO Box 162059 Fort Worth TX 76161			Product: EFFIPRO® PLUS TOPICAL SOLUTION FOR DOGS		
Ingredient: Fipronil, Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Product Chemistry Test Guidelines					
830.1550	Product Identity and Composition	New Submission	Virbac AH, Inc.	OWN	
830.1600	Description of Materials Used	New Submission	Virbac AH, Inc.	OWN	
830.1620	Description of Production Process	New Submission	Virbac AH, Inc.	OWN	
830.1650	Description of Formulation Process	New Submission	Virbac AH, Inc.	OWN	
830.1670	Description of Formation of Impurities	New Submission	Virbac AH, Inc.	OWN	
830.1700	5-Batch Analysis	New Submission	Virbac AH, Inc.	OWN	
830.1750	Certified Limits	New Submission	Virbac AH, Inc.	OWN	
830.1800	Analytical Method	New Submission	Virbac AH, Inc.	OWN	
830.6302	Color	New Submission	Virbac AH, Inc.	OWN	
830.6303	Physical State	New Submission	Virbac AH, Inc.	OWN	
830.6304	Odor	New Submission	Virbac AH, Inc.	OWN	
830.6313	Metal Stability		Virbac AH, Inc.	NR	
830.6314	Oxidation/reduction	New Submission	Virbac AH, Inc.	OWN	
830.6315	Flammability	New Submission	Virbac AH, Inc.	OWN	
830.6316	Explosibility		Virbac AH, Inc.	NR	
830.6317	Storage stability	To be conducted	Virbac AH, Inc.	OWN	
Signature 			Name and Title Craig Parks Vice President, Research & Development		Date December 20, 2011

EPA Form 8570-35 (9-97) Electronic and Paper Versions Available. Submit only Paper version.

Agency Internal Use Copy

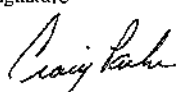
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Date December 20, 2011		EPA Reg. No./File Symbol 2382-TBA		Page 2 of 9	
Applicant's/Registrant's Name & Address Virbac AH, Inc PO Box 162059 Fort Worth TX 76161		Product: EFFIPRO® PLUS TOPICAL SOLUTION FOR DOGS			
Ingredient: Fipronil, Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7100	Viscosity	New Submission	Virbac AH, Inc.	OWN	
830.6319	Miscibility		Virbac AH, Inc.	NR	
830.6320	Corrosion characteristics	To be conducted	Virbac AH, Inc.	OWN	
830.6321	Dielectric breakdown voltage		Virbac AH, Inc.	NR	
830.7000	pH	New Submission	Virbac AH, Inc.	OWN	
830.7300	Density, bulk density, or specific gravity	New Submission	Virbac AH, Inc.	OWN	
830.7320	Particle Size distribution		Virbac AH, Inc.	NR	
40 CFR 158.340 Toxicology Data Requirements					
870.1100	Acute oral toxicity	New Submission	Virbac AH, Inc.	OWN	
870.1200	Acute dermal toxicity	New Submission	Virbac AH, Inc.	OWN	
870.1300	Acute inhalation toxicity	Waiver requested	Virbac AH, Inc.		
870.2400	Primary eye irritation	New Submission	Virbac AH, Inc.	OWN	
870.2500	Primary dermal irritation	New Submission	Virbac AH, Inc.	OWN	
870.2600	Dermal sensitization	New Submission	Virbac AH, Inc.	OWN	
Signature 			Name and Title Craig Parks Vice President, Research & Development		Date December 20, 2011

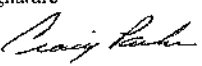
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Date: December 20, 2011			EPA Reg. No./File Symbol 2382-TBA		Page 3 of 9
Applicant's/Registrant's Name & Address Virbac AH, Inc PO Box 162059 Fort Worth TX 76161			Product: EFFIPRO® PLUS TOPICAL SOLUTION FOR DOGS		
Ingredient: Fipronil, Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Efficacy and Safety Data					
870.7200	Dog safety	43444905	Merial	OLD	
870.7200	Dog safety	43577711	Merial	OLD	
870.7200	Dog safety	43863802	Merial	OLD	
870.7200	Dog safety	43121110	Merial	OLD	
870.7200	Dog safety	43121111	Merial	OLD	
870.7200	Dog safety	45620507	Merial	PAY	
870.7200	Dog safety	43396408	Ecto Development Corporation	OLD	
870.7200	Dog safety	43612601	Ecto Development Corporation	OLD	
870.7200	Dog safety	44900902	Virbac AH, Inc.	OWN	
870.7200	Dog safety	44900903	Virbac AH, Inc.	OWN	
870.7200	Dog safety	42178309	Sumitomo Chemical Company, Ltd.	OLD	
870.7200	Dog safety	New submission	Virbac AH, Inc.	OWN	
810.3300	Efficacy	43121114	Merial	OLD	
810.3300	Efficacy	43121115	Merial	OLD	
810.3300	Efficacy	43121116	Merial	OLD	
810.3300	Efficacy	43121117	Merial	OLD	
810.3300	Efficacy	43121118	Merial	OLD	
810.3300	Efficacy	43121119	Merial	OLD	
810.3300	Efficacy	43121120	Merial	OLD	
Signature 			Name and Title Craig Parks Vice President, Research & Development		Date December 20, 2011

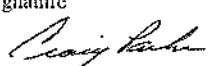
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Ingredient: Fipronil, Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Efficacy and Safety Data					
810.3300	Efficacy	43121121	Merial	OLD	
810.3300	Efficacy	43121122	Merial	OLD	
810.3300	Efficacy	43444901	Merial	OLD	
810.3300	Efficacy	43577701	Merial	OLD	
810.3300	Efficacy	43577712	Merial	OLD	
810.3300	Efficacy	43577713	Merial	OLD	
810.3300	Efficacy	43951701	Merial	OLD	
810.3300	Efficacy	44088901	Merial	OLD	
810.3300	Efficacy	46006002	Wellmark International	PUBL	
810.3300	Efficacy	44900904	Virbac AH, Inc.	OWN	
810.3300	Efficacy	45020601	Virbac AH, Inc.	OWN	
810.3300	Efficacy	Pending; submitted with Effipro Plus Cat Application		OWN	
810.3300	Efficacy	New submission		OWN	
Signature 			Name and Title Craig Parks Vice President, Research & Development		Date December 20, 2011

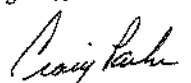
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Ingredient: Fipronil, Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
810.3300	Efficacy	44942011	Merial	PAY	
810.3300	Efficacy	44942106	Merial	PAY	
810.3300	Efficacy	45612701	Merial	PAY	
810.3300	Efficacy	45618501	Merial	PAY	
810.3300	Efficacy	45620501	Merial	PAY	
810.3300	Efficacy	45620502	Merial	PAY	
810.3300	Efficacy	45620503	Merial	PAY	
810.3300	Efficacy	45620504	Merial	PAY	
810.3300	Efficacy	45620505	Merial	PAY	
810.3300	Efficacy	45620506	Merial	PAY	
810.3300	Efficacy	45628101	Merial	PAY	
810.3300	Efficacy	45628102	Merial	PAY	
810.3300	Efficacy	45628103	Merial	PAY	
810.3300	Efficacy	45628104	Merial	PAY	
810.3300	Efficacy	45628105	Merial	PAY	
810.3300	Efficacy	45628201	Merial	PAY	
810.3300	Efficacy	45866901	Merial	PAY	
810.3300	Efficacy	45866902	Merial	PAY	
810.3300	Efficacy	46019201	Merial	PAY	
810.3300	Efficacy	46019202	Merial	PAY	
Signature 			Name and Title Craig Parks Vice President, Research & Development		Date December 20, 2011

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Ingredient: Fipronil, Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Child Resistant Packaging					
40 CFR 157	Evaluation of the 3 ml Applicator Tube with 1.34 ml water, 1 applicator tube test for Child-Resistant Effectiveness	48095221	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 3 ml Applicator Tube with 1.34 ml water, 6 applicators tube test for Child-Resistant Effectiveness	48095222	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 3 ml Applicator Tube with 1.34 ml water, 36 applicators tube test for Child-Resistant Effectiveness	48095223	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 3 ml Applicator Tube with 1.34 ml water, 1 applicator tube test for Senior-Use Effectiveness	48095224	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 3 ml Applicator Tube with 1.34 ml water, 6 applicators tube test for Senior-Use Effectiveness	48095225	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 3 ml Applicator Tube with 1.34 ml water, 36 applicators tube test for Senior-Use Effectiveness	48095226	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 3 ml Applicator Tube with 2.68ml water, 1 applicator tube test for Child-Resistant Effectiveness	48095227	Virbac AH, Inc.	OWN	
Signature 			Name and Title Craig Parks Vice President, Research & Development		Date December 20, 2011

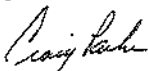
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Ingredient: Fipronil, Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
40 CFR 157	Evaluation of the 3 ml Applicator Tube with 2.68 ml water, 6 applicators tube test for Child-Resistant Effectiveness	48095228	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 3 ml Applicator Tube with 2.68 ml water, 36 applicators tube test for Child-Resistant Effectiveness	48095229	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 3 ml Applicator Tube with 2.68 ml water, 1 applicator tube test for Senior-Use Effectiveness	48095230	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 3 ml Applicator Tube with 2.68 ml water, 6 applicators tube test for Senior-Use Effectiveness	48095231	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 3 ml Applicator Tube with 2.68 ml water, 36 applicators tube test for Senior-Use Effectiveness	48095232	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 6 ml Applicator Tube with 4.02 ml water, 1 applicator tube test for Child-Resistant Effectiveness	48095233	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 6 ml Applicator Tube with 4.02 ml water, 6 applicators tube test for Child-Resistant Effectiveness	48095234	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 6 ml Applicator Tube with 4.02 ml water, 36 applicators tube test for Child-Resistant Effectiveness	48095235	Virbac AH, Inc.	OWN	
Signature 			Name and Title Craig Parks Vice President, Research & Development		Date December 20, 2011

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DATA MATRIX

Date: December 20, 2011			EPA Reg. No./File Symbol 2382-TBA		Page 8 of 9
Applicant's/Registrant's Name & Address Virbac AH, Inc. PO Box 162059 Fort Worth TX 76161			Product: EFFIPRO® PLUS TOPICAL SOLUTION FOR DOGS		
Ingredient: Fipronil, Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
40 CFR 157	Evaluation of the 1ml applicator tube with 0.67 ml water, 1 applicator tube test for Child-Resistant Effectiveness	48410001	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 1ml applicator tube with 0.67 ml water, 1 applicator tube test for Senior-Use Effectiveness	48410002	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 1ml applicator tube with 0.67 ml water, 6 applicator tube test for Child-Resistant Effectiveness	48410003	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 1ml applicator tube with 0.67 ml water, 6 applicator tube test for Senior-Use Effectiveness	48410004	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 1ml applicator tube with 0.67 ml water, 36 applicator tube test for Child-Resistant Effectiveness	48410005	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 1ml applicator tube with 0.67 ml water, 36 applicator tube test for Senior-Use Effectiveness	48410006	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 1ml applicator tube with 0.67 ml water, 3 applicator tube test for Child-Resistant Effectiveness	48410007	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 1ml applicator tube with 0.67 ml water, 3 applicator tube test for Senior-Use Effectiveness	48410008	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 3ml applicator tube with 1.34 ml water, 3 applicator tube test for Child-Resistant Effectiveness	48410009	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 3ml applicator tube with 1.34 ml water, 3 applicator tube test for Senior-Use Effectiveness	48410010	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 3ml applicator tube with 2.68 ml water, 3 applicator tube test for Child-Resistant Effectiveness	48410011	Virbac AH, Inc.	OWN	
Signature 			Name and Title Craig Parks Vice President, Research & Development		Date December 20, 2011

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Date December 20, 2011		EPA Reg. No./File Symbol 2382-TBA		Page 9 of 9	
Applicant's/Registrant's Name & Address Virbac AH, Inc PO Box 162059 Fort Worth TX 76161		Product: EFFIPRO® PLUS TOPICAL SOLUTION FOR DOGS			
Ingredient: Fipronil, Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
40 CFR 157	Evaluation of the 3ml applicator tube with 2.68 ml water, 3 applicator tube test for Senior-Use Effectiveness	48410012	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 1ml applicator tube with 4.02 ml water, 3 applicator tube test for Child-Resistant Effectiveness	48410013	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 1ml applicator tube with 4.02 ml water, 3 applicator tube test for Senior-Use Effectiveness	48410014	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 3ml applicator tube with 2.68 ml water, 1 applicator tube test for Senior-Use Effectiveness	48410015	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 3ml applicator tube with 2.68 ml water, 36 applicator tube test for Senior-Use Effectiveness	48410016	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 6ml applicator tube with 4.02 ml water, 6 applicator tube test for Senior-Use Effectiveness	48410017	Virbac AH, Inc.	OWN	
Signature 			Name and Title Craig Parks Vice President, Research & Development		Date December 20, 2011



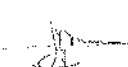
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DATA MATRIX

Date: August 23, 2011			EPA Reg No./File Symbol 87825-R		Page 1 of 6
Applicant's/Registrant's Name & Address Virbac SA 1ere avenue 2065 M - LID F-06516 Carros, France			Product: Fipronil Technical		
Ingredient: Fipronil					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Product Chemistry Test Guidelines					
830.1550	Product Identity and Composition	48095240, 48449201	Virbac	OWN	
830.1600	Description of Materials Used	48095240	Virbac	OWN	
830.1620	Description of Production Process	48095239	Virbac	OWN	
830.1650	Description of Formulation Process	48095239	Virbac	OWN	
830.1670	Description of Formation of Impurities	48095240, 48449201	Virbac	OWN	
830.1700	Preliminary Analysis	48095241	Virbac	OWN	
830.1750	Certified Limits	48095240, 48449201	Virbac	OWN	
830.1800	Analytical Method	48095242	Virbac	OWN	
830.1900	Submittal of samples		Virbac	N/A	
830.6302	Color	48095240, 48095243	Virbac	OWN	
830.6303	Physical State	48095240, 48095243	Virbac	OWN	
830.6304	Odor	48095243	Virbac	OWN	
830.6313	Accelerated Storage Stability-Metal Ions	48095243	Virbac	OWN	
830.6314	Oxidation/reduction	48095239	Virbac	OWN	
830.6315	Flammability	48095239	Virbac	OWN	
830.6316	Explosibility	48095239	Virbac	NR	
830.6317	1 Yr. Storage Stability		Virbac	OWN	See note page 2
Signature 			Name and Title Jean-Pascal Marc Corporate Product Innovation Director		Date August 23, 2011

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
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DATA MATRIX

Date August 23, 2011			EPA Reg No./File Symbol 87825-R		Page 2 of 6
Applicant's/Registrant's Name & Address Virbac SA 1ere avenue 2065 M - LID F-06516 Carros, France			Product: Fipronil Technical		
Ingredient: Fipronil					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6318	Viscosity		Virbac	N/A	
830.6319	Miscibility		Virbac	N/A	Solid
830.6320	Corrosion characteristics		Virbac	OWN	See note page 2
830.6321	Dielectric breakdown voltage		Virbac	N/A	Waived
830.7000	pH	48095247	Virbac	OWN	
830.7200	Melting Point	48095249	Virbac	OWN	
830.7300	Density bulk density or specific gravity	48095250	Virbac	OWN	
830.7320	Particle Size		Virbac	N/A	
830.7050	UV/Visible Spectrum	48095248	Virbac	OWN	
830.7370	Dissociation constant	48095251	Virbac	OWN	
830.7520;830.7550; 830.7560 830.7570	Octanol/water partition coefficient	48095244	Virbac	OWN	
830.7840;830.7860	Solubility	48095245	Virbac	OWN	
830.7950	Vapor pressure	48095246	Virbac	OWN	
Signature 			Name and Title Jean-Pascal Marc Corporate Product Innovation Director		Date August 23, 2011

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Note: 830.6317 and 830.6320: Per Agency policy, storage stability and corrosion characteristics data are not required to be submitted unless specifically requested by the Agency. Virbac has initiated these studies and will submit the final reports if required when the studies are completed.



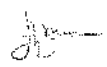
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DATA MATRIX

Date: August 23, 2011			EPA Reg No./File Symbol 87825-R		Page 3 of 6
Applicant's/Registrant's Name & Address Virbac SA 1 ere avenue 2065 M - LID F-06516 Carros, France			Product: Fipronil Technical		
Ingredient: Fipronil					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
40 CFR 158.340 Toxicology Data Requirements					
870.1100	Acute oral toxicity	42918628; 43235401 43279706	BASF	OLD	
870.1200	Acute dermal toxicity	42918629	BASF	OLD	
870.1200	Acute dermal toxicity	43235402	BASF	OLD	
870.1300	Acute inhalation toxicity	42918631	BASF	OLD	
870.2400	Primary eye irritation	42918632	BASF	OLD	
870.2500	Primary dermal irritation	42918630	BASF	OLD	
870.2600	Dermal sensitization	42918634	BASF	OLD	
870.6100	Acute delayed neurotoxicity	42918635	BASF	OLD	
870.6100	Acute delayed neurotoxicity	43559501	BASF	OLD	
870.3100	90-day oral toxicity - rodent	42918643	BASF	OLD	
870.3150	90-day oral toxicity - nonrodent	42918642	BASF	OLD	
870.3200	21-day dermal toxicity	42918644	BASF	OLD	
870.3250	90-day dermal toxicity	DATA GAP	BASF	GAP	*See below
870.6100	90-day neurotoxicity - mammal	43291703	BASF	OLD	
81-8	Neurotoxicity to Rats by Acute Oral Administration	44431801	BASF	PAY	
Signature 			Name and Title Jean-Pascal Marc Corporate Product Innovation Director		Date August 23, 2011




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Date August 23, 2011		EPA Reg No./File Symbol 87825-R		Page 4 of 6	
Applicant's/Registrant's Name & Address Virbac SA 1ere avenue 2065 M - LID F-06516 Carros, France		Product: Fipronil Technical			
Ingredient: Fipronil					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
40 CFR 158.340 Toxicology Data Requirements (Continued)					
84-2	Structural chromosomal aberration	42918680	BASF	OLD	
84-2	Structural chromosomal aberration	42918653	BASF	OLD	
84-2	Other genotoxic effects	42918651;42918653 43501703	BASF	OLD	
85-1/870.7485	General metabolism	42918655	BASF	OLD	
85-1/870.7485	General metabolism	43253701	BASF	PAY	
85-1/870.7485	General metabolism	43737308	BASF	OLD	
85-1/870.7485	General metabolism	42918654	BASF	OLD	
85-1/870.7485	General metabolism	42977904	BASF	OLD	
85-1/870.7485	General metabolism	43253701	BASF	OLD	
85-2/870.7600	Dermal penetration	43737308	BASF	PAY	
85-7/870.7600	Immunotoxicity	DATA GAP		GAP	*See below
40 CFR 158.490 Wildlife and Aquatic Organisms Data Requirements					
71-1/850.2100	Avian oral LD 50 -- mallard or bobwhite	42918617 42918616	BASF	OLD	
72-1/850.1075	Freshwater fish LC 50 -- rainbow or bluegill	42918624;42918673; 42918674;42977902 43279703;43291718	BASF	OLD OLD OLD	
Signature 			Name and Title Jean-Pascal Marc Corporate Product Innovation Director		Date August 23, 2011

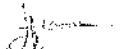
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Date: August 23, 2011			EPA Reg. No./File Symbol 87825-R		Page 5 of 6
Virbac SA 1 rue avenue 2065 M - LID F-06516 Carros, France			Product: Fipronil Technical		
Ingredient: Fipronil					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
83-1/870.4100	Chronic feeding – rodent	42918648	BASF	OLD	
83-1/870.4100	Chronic feeding – nontodent	42918645	BASF	OLD	
83-1/870.4100	Chronic feeding – nonrodent	43402802	BASF	PAY	
83-2/870.4200	Oncogenicity – mouse	42918649	BASF	OLD	
83-2/870.4200	Oncogenicity – mouse	43501702	BASF	PAY	
83-2/870.4200	Oncogenicity – rat	42918648	BASF	OLD	
83-3/870.3700	Teratogenicity – rabbit	42918646	BASF	OLD	
83-3/870.3700	Teratogenicity – rat	42977903	BASF	OLD	
83-3/870.3700	Teratogenicity – rat	44275001	BASF	PAY	
83-6/870.6300	Developmental neurotoxicity	44039002	BASF	PAY	
83-4/870.3800	Reproduction	42918647	BASF	OLD	
84-2/870.5100	Gene mutation	42918652	BASF	OLD	
84-2/870.5100	Gene mutation	42918679	BASF	OLD	
84-2/870.5100	Gene mutation	43291716	BASF	OLD	
84-2/870.5100	Gene mutation	43291717	BASF	OLD	
84-2/870.5100	Gene mutation	43291721	BASF	OLD	
84-2/870.5100	Gene mutation	43291722	BASF	OLD	
84-2/870.5100	Gene mutation	43401102	BASF	OLD	
Signature 			Name and Title Jean-Pascal Marc Corporate Product Innovation Director		Date August 23, 2011

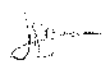


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Applicant's/Registrant's Name & Address Virbac SA Iere avenue 2065 M - LID F-06516 Carros, France			Product: Fipronil Technical		
Ingredient: Fipronil					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
72-2/850.1010	Acute LC 50 freshwater invertebrates (<i>Daphnia magna</i>)	42918625	BASF	OLD	
	Acute LC 50 freshwater invertebrates (<i>Daphnia magna</i>)	42918669	BASF	OLD	
	Acute LC 50 freshwater invertebrates (<i>Daphnia magna</i>)	42918671	BASF	OLD	
	Acute LC 50 freshwater invertebrates (<i>Daphnia magna</i>)	43291719	BASF	OLD	
835.2110	Hydrolysis	42977905	BASF	OLD	
40 CFR 158.390 Reentry Protection Data Requirements					
133-3	Dermal exposure - Fipronil	44433302	Merial	PAY	
133-4	Inhalation exposure - Fipronil	44433302	Merial	PAY	
132-1	Dislodgeable residue dissipation - Fipronil	44531203	Merial	PAY	
N/A	Dermal and inhalation exposure of commercial pet groomers (Spot) - Fipronil	44433303	Merial	PAY	
N/A	Analytical method for exposure studies - Fipronil	44433308	Merial	PAY	
Signature 			Name and Title Jean-Pascal Mare Corporate Product Innovation Director		August 23, 2011

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* Pursuant to 40 CFR 152.96 (c), Virbac hereby certifies that Virbac has no basis to believe that this requirement is not a data gap and, further, that Virbac has sent by certified mail to all companies on the current EPA Data Submitters List for fipronil a letter requesting that the company identify, within 60 days of receipt, any valid study that would fulfill this data requirement. Once this 60-day period expires, Virbac will update the Agency as to the information, if any, Virbac receives in response to this "data gap" letter.

Receipt for Section 3							
S:	916101	Resubmission:	<input type="radio"/> Yes <input checked="" type="radio"/> No				
Regulatory Type:	Product Registration - Section 3	Fee For Service:	<input type="radio"/> Yes <input checked="" type="radio"/> No				
Application Type:	Pending Product Amendment	Billable:	<input checked="" type="radio"/> Yes <input type="radio"/> No				
Company:	2596 THE HARTZ MOUNTAIN CORPORATION		V				
Risk Manager:	Registration Division, Risk Management Team 10						
Product #:	2596-RAG	Product Name:	HARTZ REFERENCE #128				
Override#:							
Me Too Section3:		Me Too Product Name:					
Application Date:	27-Apr-2012	OPP Rec'd Date:	01-May-2012				
Front End Date:	01-May-2012	Risk Manager Send Date:	02-May-2012				
FFS Due Date:		Negotiated Due Date:					
OPP Target Date:							
Fast Track:	<input type="checkbox"/>	New Ingredient:	<input type="checkbox"/>				
Receipt Description:	Label Amendment						
Form A:	<input type="checkbox"/>	Signature Date:					
Form B:	<input type="checkbox"/>	Signature Date:					
		New Ingredient Request Date:					
		New Ingredient Received Date:					
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		<table border="1"> <thead> <tr> <th>Receipt Content</th> <th>Des</th> </tr> </thead> <tbody> <tr> <td>Paper Label</td> <td></td> </tr> </tbody> </table>		Receipt Content	Des	Paper Label	
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Resubmission

Fee for Service

{916101b~

This package includes the following

- ☐ New Registration
- ☒ Amendment

- ☐ Studies? ☐ Fee Waiver?
- ☐ volpay % Reduction: ____

for Division

- ☐ AD
- ☐ BPPD
- ☒ RD

Risk Mgr. 10

Receipt No.

S-

916101

EPA File Symbol/Reg. No.

2596-RAG

Pin-Punch Date:

4/30/2012

☒ This item is NOT subject to FFS action.

Action Code:

Requested:

Granted:

Amount Due: \$ ____

Parent/Child Decisions:

☒ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: *Emily Ann Oliver*

Date: *5/2/12*

Remarks: *Resubmission*



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

May 2, 2012

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

LANCE HEMSARTH
THE HARTZ MOUNTAIN CORPORATION
400 PLAZA DRIVE
SECAUCUS, NJ 07094-

PRODUCT NAME: HARTZ REFERENCE #129
COMPANY NAME: THE HARTZ MOUNTAIN CORPORATION
OPP IDENTIFICATION NUMBER:
EPA FILE SYMBOL: 2596-RAU
EPA RECEIPT DATE: 05/01/12

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Registration Division, Risk Management Team 10, at (703) 305-6701.

Sincerely,

A handwritten signature in black ink, appearing to read "S. J. J.", is placed above the typed name of the sender.

Front End Processing Staff
Information Services Branch
Information Technology & Resources Management Division



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 2596-RAG	2. EPA Product Manager Richard Gebken	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Hartz Ref. 128	PM# 10	
5. Name and Address of Applicant (Include ZIP Code) The Hartz Mountain Corporation 400 Plaza Drive, Secaucus, NJ 07094 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Mo Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input checked="" type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Label change based on the feedback from Rosalind Gross. Changes made to the master label directions for use to be exactly the same as the instructions for the child resistant packaging (CRP) test.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input checked="" type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt. No. per container		
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Sean McNear		Title Director Reg. Affairs	
		Telephone No. (Include Area Code) 201-271-4800	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)
2. Signature 		3. Title Director Regulatory Affairs	
4. Typed Name Sean McNear		5. Date April 27, 2012	

DATA EVALUATION RECORD

PYRIPROXYFEN AND FIPRONIL

[104.11; EFFIPRO® PLUS TOPICAL SOLUTION FOR DOGS]

STUDY TYPE: ACUTE ORAL TOXICITY - RAT [OCSP 870.1100; OECD 425]

ACUTE DERMAL TOXICITY - RAT [OCSP 870.1200; OECD 402]

ACUTE EYE IRRITATION - RABBIT [OCSP 870.2400; OECD 405]

ACUTE DERMAL IRRITATION - RABBIT [OCSP 870.2500; OECD 404]

DERMAL SENSITIZATION - GUINEA PIG [OCSP 870.2600; OECD 406]

MRID: 486969-10, 486969-11, 486969-12, 486969-13, and 486969-14

Prepared for
Registration Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Prepared by
Summitec Corporation
9724 Kingston Pike, Suite 602
Knoxville, Tennessee 37922

Task Order No. 3-C-10

Primary Reviewer:

Donna L. Fefee, D.V.M.

Signature: Donna L. Fefee, AE

Date: APR 16 2012

Secondary Reviewers:

Thomas C. Marshall, Ph.D., D.A.B.T.

Signature: Thomas C. Marshall, AE

Date: APR 16 2012

Robert H. Ross, M.S., Program Manager

Signature: Robert H. Ross

Date: APR 16 2012

Quality Assurance:

Angela M. Edmonds, B.S.

Signature: Angela M. Edmonds

Date: APR 16 2012

Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

chewing gum, using tobacco or using the toilet. Wear long-sleeved shirt and long pants, socks, shoes, and gloves. Remove and wash contaminated clothing before reuse. [Wear protective eyewear.]*

*[Protective eyewear may be specified, if appropriate].

First Aid:

If on skin:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

If swallowed:

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything to an unconscious person.

If in eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- Call a poison control center or doctor for treatment advice.

NOTE TO PHYSICIAN: Note to PM/CRM/Registrant: The proposed label should contain a "Note to Physician". The following statements are suggested types of information that may be included, if applicable: - technical information on symptomatology; - use of supportive treatments to maintain life functions; - medicine that will counteract the specific physiological effects of the pesticide; - company telephone number to specific medical personnel who can provide specialized medical advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

5. The basic CSF dated October 21, 2011 for 2382-RIO should be reviewed and accepted by the TRB Chemistry Team.

BACKGROUND:

The material received for review includes a proposed label, indicating the product is packaged in single-use applicators (1, 3, 6 or 36 applicators per package). Dosage rates are stated to be 0.023 fl. oz. (0.67 mL) "for small dogs and puppies 8 weeks old or older and up to 22.9 lbs," 0.045 fl. oz. (1.34 mL) for dogs weighing 23-44.9 lbs, 0.091 fl. oz. (2.68 mL) for dogs weighing 45-88.9 lbs, and 0.136 fl. oz. (4.02 mL) for dogs weighing 89-132 lbs. The product is to be applied no more frequently than once a month ("Effective monthly control of fleas and ticks," and "Once monthly application." There are five acute toxicity studies (MRID 48696910, acute oral toxicity study in rats; 48696911, acute dermal toxicity study in rats; 48696912, acute eye irritation study in rabbits; 48696913, acute dermal irritation study in rabbits; and 48696914, contact hypersensitivity in albino guinea pigs, Buehler test), and a waiver request for the inhalation toxicity study requirement. In addition, there is a basic CSF, dated October 21, 2011.

COMMENTS AND RECOMMENDATIONS:

1. The acute toxicity studies in MRIDs 48696910-48696914 were reviewed by a contractor, Summetic. The resulting DER was reviewed by TRB, and the appropriate revisions, if necessary, were made. It is concluded that these five acute toxicity studies are acceptable, and can be used to support the registration of 2382-RIO.
2. TRB has reviewed the acute inhalation toxicity study waiver request, and concludes that, based on the proposed product use and minimal potential inhalation exposure, this study can be waived and the product can be assigned to Toxicity Category IV by the inhalation exposure route.
3. Based on the results of the acute toxicity studies, the following is the acute toxicity profile for 2382-RIO (EFFIPRO® PLUS TOPICAL SOLUTION FOR DOGS):

Acute oral toxicity	III	Acceptable	MRID 48696910
Acute dermal toxicity	III	Acceptable	MRID 48696911
Acute inhalation toxicity	IV	Waived	n/a
Primary eye irritation	III	Acceptable	MRID 48696912
Primary dermal irritation	IV	Acceptable	MRID 48696913
Dermal sensitization	Negative	Acceptable	MRID 48696914

4. Based on the acute toxicity profile above, the following is the precautionary and first aid labeling for 2382-RIO, as obtained from the TRB Label Review System.

PRODUCT ID #: 002382-00189

PRODUCT NAME: EFFIPRO® PLUS TOPICAL SOLUTION FOR DOGS

PRECAUTIONARY STATEMENTS

SIGNAL WORD: CAUTION

Hazards to Humans and Domestic Animals:

Harmful if absorbed through skin. Harmful if swallowed. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking,



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

May 15, 2012

MEMORANDUM

Subject: Name of Pesticide Product: EFFIPRO® PLUS TOPICAL SOLUTION FOR DOGS
EPA Reg. No. /File Symbol: 2382-RIO
DP Barcode: DP 398341
Decision No.: 459013
Action Code: R310
PC Codes: 129032 (Pyriproxyfen: 2.9%)
129121 (Fipronil: 9.7%)

From: Byron T. Backus, Ph.D., Toxicologist
Technical Review Branch
Registration Division (7505P)

Byron T. Backus
May 15, 2012

M. Hashmi - Team Leader
5-15-12 /Tox

To: Bonaventure Akinlosotu/Richard Gebken RM 10
Insecticide Branch
Registration Division (7505P)

Registrant: VIRBAC AH, INC.

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>by wt.</u>
129121 Fipronil	9.7%
129032 Pyriproxyfen	2.9%
<u>Other Ingredient(s):</u>	<u>87.4%</u>
TOTAL	100.0%

ACTION REQUESTED: The Risk Manager requests:

"For your review: R310. MRID 486969-10 to -14; for a Fipronil + Pyriproxyfen containing Spot-On for dogs. Submits prod chem., tox, efficacy and CAS data..."

Acute dermal toxicity / rat Harlan Laboratories Ltd. (Itingen, Switzerland) Study #D34677 / November 18, 2011 OCSP 870.1200; OECD 402	48696911	LD ₅₀ > 2000 mg/kg (both sexes) No deaths, abnormal systemic clinical signs, or abnormal gross findings; BW affected: 4/5 males and 4/5 females lost weight during days 1-8, all animals gained during days 8-15 and most had net BW gain over days 1-15 (1 female had net loss over days 1-15); local effects: erythema on 1 male on day 2 (resolved by day 3), desquamation and/or focal crusts on 5/5 males and 4/5 females beginning days 2-6 (resolved by day 15 except desquamation in 1 male and 1 female). <i>Note: It is unclear whether the size of the dose site really was 10% of the body surface area (BSA). The study author stated that application sites were approximately 10% of body surface area, but it was also stated that application sites were covered by a gauze pad measuring ~25 cm², which, according to standard formulas, would be less than 10% of the BSA for rats in the BW range used in this study (193.7- 276.8).</i> <i>Deficiency: Systemic clinical signs data from days 2-15 were omitted from the study report.</i>	III	A
Acute inhalation toxicity / rat	n.a.	Waiver recommended on basis of product use (pet spot-on) and minimal inhalation exposure.	(IV)	W
Primary eye irritation / rabbit Harlan Laboratories Ltd. (Itingen, Switzerland) Study #D34688 / November 30, 2011 OCSP 870.2400; OECD 405	48696912	Use of anesthetic not mentioned. No corneal or iridial effects seen in any eye at any time point. Conjunctival redness present in 3/3 eyes at 1 hr through 7 days and in 2/3 and 1/3 eyes at 10 and 14 days post instillation (score=1-2). Conjunctival discharge seen in 2 eyes at 1 hour (score=1) and not seen thereafter. Slight to moderate scleral reddening seen in 3 eyes at 1 hour and in 2 eyes at 24-72 hours. Conjunctivitis scored as "positive" in 2/3 eyes at 24-48 hrs and in 1/3	III	A

EPA Reviewer: Byron T. Backus, Ph.D.
Risk Manager (EPA): 10

Date: May 15, 2012

The following table is the Acute Toxicity Data Evaluation Record (DER) for the five studies submitted for the proposed product, File Symbol 2382-RIO

1. DP BARCODE: 398341				
2. PC CODES: 129032 and 129121				
3. CURRENT DATE: May 15, 2012				
4. TEST MATERIAL: 104.11; Batch #FMA 11123-1; 9.68% Fipronil and 2.98% Pyriproxyfen (per certificate of analysis); yellow odourless liquid (or colorless to yellowish liquid); density: 1.036 g/mL; pH: 4-5 (MRID 48696912); expiration date: November 2011; stored at room temperature				
Study/Species/Lab Study # /Date	MRID	Results	Tox Cat	Core Grade
Acute oral toxicity / rat Harlan Laboratories Ltd. (Itingen, Switzerland) Study #D34666 / November 18, 2011 OCSPP 870.1100; OECD 425	48696910	LD ₅₀ Females = 2000 mg/kg bw [95% PL Confidence interval is 0 to >20,000] Four tested (with dosing on day 1) in accordance with AOT425 StatPgm (assumed sigma=0.5): 1 at 550 mg/kg, 3 at 2000 mg/kg. 550 mg/kg: no deaths, abnormal clinical signs, bw effects, or gross findings. 2000 mg/kg: 2 deaths (days 6 & 9); clinical signs: ruffled fur and/or hunched posture in 2/3 (day 1); survivor lost wt days 1-8 but had net gain for the study overall; gross necropsy findings limited to lung congestion in both decedents. <i>Deviation from OECD 425: no rationale provided for use of starting dose different from default.</i>	III	A

		eyes at 72 hours. MMTS=3.33, at 1-48 hours; Mildly irritating (per Kay and Calandra). Classified based on resolution of "positive" irritation within 7 days or less.		
Primary dermal irritation / rabbit Harlan Laboratories Ltd. (Ittingen, Switzerland) Study #D34690 / November 30, 2011 OCSP 870.2500; OECD 404	48696913	PD1 at 72 hours=0.00 There were no observations of erythema, edema, or other changes to the skin on any animal at any time point. "Nonirritant" based on US EPA (1988).	IV	A
Dermal sensitization / guinea pig Harlan Laboratories Ltd. (Fullinsdorf, Switzerland) Study #D34701 / October 27, 2011 OCSP 870.2600; OECD 406	48696914	Tested using Buehler method Induction used 100% concentration; challenge used 75% concentration in diethylene glycol monoethyl ether vehicle. No positive dermal reactions on treated or vehicle control animals following challenge. <i>Not a sensitizer</i> <i>Deficiencies: Justification not provided for usage of non-standard vehicle. It appears that in the positive control study the testing lab was not able to identify the HNIC; two challenge concentrations (neither of which was a HNIC) were selected, based, in part, upon historical results. Results of initial challenge were equivocal, and a re-challenge was necessary. "Correct" results were attained, but the laboratory has not necessarily demonstrated proficiency.</i>	--	A

Core Grade Key: A =Acceptable, S = Supplementary, U = Unacceptable, D = Data Gap, W = Waived

DATA PACKAGE BEAN SHEET

Date: 02-Feb-2012

Page 1 of 2

Decision #: 459013

DP #: (398344)

PRIA

Parent DP #:

Submission #: 908748

E-Sub #:

*** Registration Information ***

Registration: 2382-RIO - EFFIPRO PLUS TOPICAL SOLUTION FOR DOGS

Company: 2382 - VIRBAC AH, INC.

Risk Manager: RM 10 - Richard Gebken - (703) 305-6701 Room# PY1 S-7237

Risk Manager Reviewer: Bonaventure Akinlosotu BAKINLOS

Sent Date:

Calculated Due Date: 10-Jul-2012

Edited Due Date:

Type of Registration: Product Registration - Section 3

Action Desc: (R310) NEW PRODUCT;NON-FAST TRACK (INCLUDES REVIEWS OF PRODUCT CHEMIST

Ingredients: 129032, Pyriproxyfen(2.9%)

129121, Fipronil(9.7%)

*** Data Package Information ***

Expedite: ☐ Yes ☒ No

Date Sent: 02-Feb-2012

Due Back:

DP Ingredient: 129121, Fipronil

129032, Pyriproxyfen

DP Title: tox/cas

CSF Included: ☒ Yes ☐ No

Label Included: ☒ Yes ☐ No

Parent DP #:

Assigned To

Date In

Date Out

Organization: RD / TRB

Last Possible Science Due Date: 10-Jun-2012

Team Name: TOX

Science Due Date:

Reviewer Name: Backus, Byron

Sub Data Package Due Date:

Contractor Name:

*** Studies Sent for Review ***

Printed on Page 2

*** Additional Data Package for this Decision ***

Can be printed on its own page

*** Data Package Instructions ***

For your review: R310

MRID 48696916; for a Fipronil + Pyriproxyfen containing Spot-On for dogs.

Submits prod chem, tox, efficacy and CAS data; Cites CRP data.

Thanks, B.A

CAS
Summary
Byron

DP#: (398344)

*** Studies Sent for Review ***

Decision#: (459013)

MRID	MRID Status	Citation Reference	Guideline	RR-S Status
48696916		Villard, I. (2011) Summary of Companion Animal Safety Data for Effipro Plus Topical Solution for Dogs (Fipronil 9.7% and Pyriproxyfen 2.9% End Use Product). Project Number: VIRBAC/104/11/1. Unpublished study prepared by Isa Vet Biosciences 51p.	870.7200/Companion animal safety	Pass (10-Jan-2012)

DATA PACKAGE BEAN SHEET

Date: 02-Feb-2012

Page 1 of 2

Decision #: 459013

DP #: (398341)

PRIA

Parent DP #:

Submission #: 908748

E-Sub #:

*** Registration Information ***

Registration: **2382-RIO - EFFIPRO PLUS TOPICAL SOLUTION FOR DOGS**

Company: 2382 - VIRBAC AH, INC.

Risk Manager: RM t0 - Richard Gebken - (703) 305-6701 Room# PY1 S-7237

Risk Manager Reviewer: Bonaventure Akinlosotu BAKINLOS

Sent Date:

Calculated Due Date: 10-Jul-2012

Edited Due Date:

Type of Registration: Product Registration - Section 3

Action Desc: (R310) NEW PRODUCT;NON-FAST TRACK (INCLUDES REVIEWS OF PRODUCT CHEMIST

Ingredients: t29032, Pyriproxyfen(2.9%)

129121, Fipronil(9.7%)

*** Data Package Information ***

Expedite: ☐ Yes ☒ No

Date Sent: 02-Feb-2012

Due Back:

DP Ingredient: 129032, Pyriproxyfen

129121, Fipronil

DP Title: tox/pl

CSF Included: ☒ Yes ☐ No

Label Included: ☒ Yes ☐ No

Parent DP #:

Assigned To

Date In

Date Out

Organization: RD / TRB

Last Possible Science Due Date: 10-Jun-2012

Team Name: TOX

Science Due Date:

Reviewer Name: Backus, Byron

Sub Data Package Due Date:

Contractor Name: Summatic

*** Studies Sent for Review ***

Printed on Page 2

*** Additional Data Package for this Decision ***

Can be printed on its own page

*** Data Package Instructions ***

For your review: R310

MRID 486969 - t0 to -t4; for a Fipronil + Pyriproxyfen containing Spot-On for dogs.

Submits prod chem, tox, efficacy and CAS data; Cites CRP data.

Thanks, B.A

DP#: (398341)

*** Studies Sent for Review ***

Decision#: (459013)

MRID	MRID Status	Citation Reference	Guideline	MRID Status
48696910		Damme, B. (2011) 104.11: Acute Oral Toxicity Study in Rats - Up-and-Down Procedure: Final Report. Project Number: D34666. Unpublished study prepared by Harlan Laboratories, Ltd. 69p.	870.1100/Acute Oral Toxicity	Pass (10-Jan-2012)
48696911		Damme, B. (2011) 104.11: Acute Dermal Toxicity Study in Rats: Final Report. Project Number: D34677. Unpublished study prepared by Harlan Laboratories, Ltd. 66p.	870.1200/Acute dermal toxicity	Pass (10-Jan-2012)
48696912		Damme, B. (2011) 104.11: Acute Eye Irritation Study in Rabbits: Final Report. Project Number: D34688. Unpublished study prepared by Harlan Laboratories, Ltd. 72p.	870.2400/Acute eye irritation	Pass (10-Jan-2012)
48696913		Damme, B. (2011) 104.11: Acute Dermal Irritation Study in Rabbits: Final Report. Project Number: D34690. Unpublished study prepared by Harlan Laboratories, Ltd. 55p.	870.2500/Acute dermal irritation	Pass (10-Jan-2012)
48696914		Arcelin, G. (2011) 104.11: Contact Hypersensitivity in Albino Pigs, Buehler Test: Final Report. Project Number: D34701. Unpublished study prepared by Harlan Laboratories, Ltd. 101p.	870.2600/Skin sensitization	Pass (10-Jan-2012)

DATA PACKAGE BEAN SHEET

Date: 02-Feb-2012

Page 1 of 2

Decision #: 459013

DP #: (398341)

PRIA

Parent DP #:

Submission #: 908748

E-Sub #:

*** Registration Information ***

Registration: **2382-RIO - EFFIPRO PLUS TOPICAL SOLUTION FOR DOGS**

Company: 2382 - VIRBAC AH, INC.

Risk Manager: RM 10 - Richard Gebken - (703) 305-6701 Room# PY1 S-7237

Risk Manager Reviewer: Bonaventure Akinlosotu BAKINLOS

Sent Date:

Calculated Due Date: 10-Jul-2012

Edited Due Date:

Type of Registration: Product Registration - Section 3

Action Desc: (R310) NEW PRODUCT;NON-FAST TRACK (INCLUDES REVIEWS OF PRODUCT CHEMIST

Ingredients: 129032, Pyriproxyfen(2.9%)

129121, Fipronil(9.7%)

*** Data Package Information ***

Expedite: ☐ Yes ☒ No

Date Sent: 02-Feb-2012

Due Back:

DP Ingredient: 129032, Pyriproxyfen

129121, Fipronil

DP Title: tox/pl

CSF included: ☒ Yes ☐ No

Label Included: ☒ Yes ☐ No

Parent DP #:

Assigned To

Date in

Date Out

Organization: RD / TRB

Last Possible Science Due Date: 10-Jun-2012

Team Name: TOX

Science Due Date:

Reviewer Name: Backus, Byron

Sub Data Package Due Date:

Contractor Name:

*** Studies Sent for Review ***

Printed on Page 2

*** Additional Data Package for this Decision ***

Can be printed on its own page

*** Data Package Instructions ***

For your review: R310

MRID 486969 - 10 to -14; for a Fipronil + Pyriproxyfen containing Spot-On for dogs.

Submits prod chem, tox, efficacy and CAS data; Cites CRP data.

Thanks, B.A

INHALATION WAIVER REQUEST
WILL BE HANDLED BY TRB.

Waiver Request

Registrant: Virbac Animal Health, Inc.
Acute Inhalation Study (OPPTS 830.1300).
Effipro Plus Topical Solution for Dogs.

The Effipro[®] Plus Topical Solution for Dogs product is composed of 9.7% w/w of the active ingredient fipronil and 2.9 % w/w of the active ingredient pyriproxifen. This product is packaged in single use non-refillable applicators that are intended for one time only spot-on applications to dogs.

The potential human inhalation exposure to this product is expected to be negligible. Only very small amounts of product are applied per application, depending the weight of the animal. Based on packaging considerations described in the proposed product labeling, the maximum volume of Effipro[®] Plus Topical Solution for Dogs that can be administered at one time to a dog using the largest available applicator size is approximately 4.0 ml. This application volume represents the worst case because it is the dose that is recommended only for use on dogs weighing more than 89 pounds. Therefore, according to the proposed label, a great deal of anticipated product use will occur at much lower volumes on smaller dogs.

Furthermore, the measured vapor pressure of both of the active ingredients, fipronil and pyriproxifen, are extremely low (2.8×10^{-9} mm Hg at 25°C and 1.0×10^{-7} mm Hg at 25°C, respectively), indicating that both active ingredients are essentially non-volatile and are therefore not expected to vaporize from the skin of the treated animal following application. The active ingredients will therefore not be available for inhalation after application according to label directions. Finally, the method of applying the liquid product directly to the pet creates no particulates, aerosols, or other respirable matter. Therefore, based on the criteria provided by the Agency in 40 CFR 158.500, footnote 4 under the Toxicology Data Requirements, a waiver of the acute inhalation study for these products is appropriate.

DATA PACKAGE BEAN SHEET

Date: 02-Feb-2012

Page 1 of 2

Decision #: 459013

DP #: (398340)

PRIA

Parent DP #:

Submission #: 908748

E-Sub #:

*** Registration Information ***

Registration: 2382-RIO - EFFIPRO PLUS TOPICAL SOLUTION FOR DOGS

Company: 2382 - VIRBAC AH, INC.

Risk Manager: RM 10 - Richard Gebken - (703) 305-6701 Room# PY1 S-7237

Risk Manager Reviewer: Bonaventure Akinlosotu BAKINLOS

Sent Date: _____

Calculated Due Date: 10-Jul-2012

Edited Due Date: _____

Type of Registration: Product Registration - Section 3

Action Desc: (R310) NEW PRODUCT;NON-FAST TRACK (INCLUDES REVIEWS OF PRODUCT CHEMIS1

Ingredients: 129032, Pyriproxyfen(2.9%)

129121, Fipronil(9.7%)

*** Data Package Information ***

Expedite: ☐ Yes ☒ No

Date Sent: 02-Feb-2012

Due Back: _____

DP Ingredient: 129032, Pyriproxyfen

129121, Fipronil

DP Title: prod chem

CSF Included: ☒ Yes ☐ No

Label Included: ☒ Yes ☐ No

Parent DP #: _____

Assigned To

Date In

Date Out

Organization: RD / TRB

Last Possible Science Due Date: 10-Jun-2012

Team Name: CHEM

Science Due Date: _____

Reviewer Name: _____

Sub Data Package Due Date: _____

Contractor Name: _____

*** Studies Sent for Review ***

Printed on Page 2

*** Additional Data Package for this Decision ***

No Additional Data Packages

*** Data Package Instructions ***

For your review: R310

MRID 486969 - 01 to -09; for a Fipronil + Pyriproxyfen containing Spot-On for dogs.

Submits prod chem, tox, efficacy and CAS data; Cites CRP data.

Thanks, B.A

R310
II-30003

DP#: (398340)

*** Studies Sent for Review ***

Decision#: (459013)

MRID	MRID Status	Citation Reference	Guideline	MRID Status
48696908		Zepperitz, C. (2011) (Effipro Plus Topical Solution for Dogs): Quantification of the Active Ingredients Fipronil and Pyriproxyfen in Five Batches by Validated Methods: Final Report. Project Number: D34802. Unpublished study prepared by Harlan Laboratories Ltd. 56p.	830.1800/Enforcement analytical method	Pass (10-Jan-2012)
48696909		Zepperitz, C. (2011) 104.11: Enforcement Analytical Method - Quantification of the Active Ingredients Fipronil and Pyriproxyfen: Final Report. Project Number: D34813. Unpublished study prepared by Harlan Laboratories, Ltd. 38p.	830.1800/Enforcement analytical method	Pass (10-Jan-2012)

MRID	MRID Status	Citation Reference	Guideline	MRID Status
48696901		Villard, I. (2011) Product Specific Chemistry for Effipro Plus Topical Solution for Dogs. Project Number: VIRBAC/104/11/3. Unpublished study prepared by Virbac. 40p.	830.1550/Product identity and composition	Pass (10-Jan-2012)
48696901		Villard, I. (2011) Product Specific Chemistry for Effipro Plus Topical Solution for Dogs. Project Number: VIRBAC/104/11/3. Unpublished study prepared by Virbac. 40p.	830.1600/Description of materials used to produce the product	Pass (10-Jan-2012)
48696901		Villard, I. (2011) Product Specific Chemistry for Effipro Plus Topical Solution for Dogs. Project Number: VIRBAC/104/11/3. Unpublished study prepared by Virbac. 40p.	830.1620/Description of production process	Pass (10-Jan-2012)
48696901		Villard, I. (2011) Product Specific Chemistry for Effipro Plus Topical Solution for Dogs. Project Number: VIRBAC/104/11/3. Unpublished study prepared by Virbac. 40p.	830.1650/Description of formulation process	Pass (10-Jan-2012)
48696901		Villard, I. (2011) Product Specific Chemistry for Effipro Plus Topical Solution for Dogs. Project Number: VIRBAC/104/11/3. Unpublished study prepared by Virbac. 40p.	830.1670/Discussion of formation of impurities	Pass (10-Jan-2012)
48696901		Villard, I. (2011) Product Specific Chemistry for Effipro Plus Topical Solution for Dogs. Project Number: VIRBAC/104/11/3. Unpublished study prepared by Virbac. 40p.	830.1750/Certified limits	Pass (10-Jan-2012)
48696902		Habeck, C. (2011) 104.11: Determination of the Physico-Chemical Property "Appearance (Color, Physical State and Odor)": Final Report. Project Number: D34892. Unpublished study prepared by Harlan Laboratories, Ltd. 24p.	830.6302/Color	Pass (10-Jan-2012)
48696902		Habeck, C. (2011) 104.11: Determination of the Physico-Chemical Property "Appearance (Color, Physical State and Odor)": Final Report. Project Number: D34892. Unpublished study prepared by Harlan Laboratories, Ltd. 24p.	830.6303/Physical state	Pass (10-Jan-2012)
48696902		Habeck, C. (2011) 104.11: Determination of the Physico-Chemical Property "Appearance (Color, Physical State and Odor)": Final Report. Project Number: D34892. Unpublished study prepared by Harlan Laboratories, Ltd. 24p.	830.6304/Odor	Pass (10-Jan-2012)
48696903		Habeck, C. (2011) 104.11: Determination of Oxidation / Reduction (Chemical Incompatibility): Final Report. Project Number: D34870. Unpublished study prepared by Harlan Laboratories, Ltd. 28p.	830.6314/Oxidizing or reducing action	Pass (10-Jan-2012)
48696904		Habeck, C. (2011) 104.11: Determination of the Physico-Chemical Property "Flash Point": Final Report. Project Number: D34881. Unpublished study prepared by Harlan Laboratories, Ltd. 29p.	830.6315/Flammability	Pass (10-Jan-2012)
48696905		Habeck, C. (2011) 104.11: Determination of the Physico-Chemical Property "pH": Final Report. Project Number: D34868. Unpublished study prepared by Harlan Laboratories, Ltd. 27p.	830.7000/pH	Pass (10-Jan-2012)
48696906		Habeck, C. (2011) 104.11: Determination of the Physico-Chemical Property "Viscosity": Final Report. Project Number: D34846. Unpublished study prepared by Harlan Laboratories, Ltd. 29p.	830.7100/Viscosity	Pass (10-Jan-2012)
48696907		Habeck, C. (2011) 104.11: Determination of the Physico-Chemical Property "Relative Density": Final Report. Project Number: D34857. Unpublished study prepared by Harlan Laboratories, Ltd. 30p.	830.7300/Density/relative density	Pass (10-Jan-2012)
48696908		Zepperitz, C. (2011) (Effipro Plus Topical Solution for Dogs): Quantification of the Active Ingredients Fipronil and Pyriproxyfen in Five Batches by Validated Methods: Final Report. Project Number: D34802. Unpublished study prepared by Harlan Laboratories Ltd. 56p.	830.1700/Preliminary analysis	Pass (10-Jan-2012)

Chemical: PYRIPROXYFEN		PC Code: 129032
MRID No.	Citation in OSRI	Selected Endocrine Related Findings
42178310 43413202 43210501 43413201	<u>Study Type:</u> Carcinogenicity <u>Classification:</u> Minimum <u>Year:</u> 1991 <u>Species:</u> Mice <u>Strain:</u> Crl:CD-1 (ICR) BR <u>Sex:</u> Male and Female <u>Age at Initiation:</u> 29 days	<u>Dose levels tested:</u> 0, 22, 90 and 410 mg/day in the diet for 78 weeks. <u>Organ weights:</u> No treatment-related changes were seen in absolute or relative weights of the testes, ovaries, and adrenal glands. <u>Histopathology:</u> No treatment-related histopathological lesions were seen in the testes, ovaries, uterus, mammary, thyroid, adrenal or pituitary glands.
42178309	<u>Study Type:</u> Chronic Toxicity/ <u>Classification:</u> Guideline <u>Year:</u> 1991 <u>Species:</u> Dog <u>Strain:</u> Beagle <u>Sex:</u> Male and Female <u>Age at Initiation:</u> 23-27 weeks	<u>Dose levels tested:</u> 0, 30, 100, 300 and 1000 mg/kg/day the diet for 54 weeks. <u>Organ weights:</u> No treatment-related changes were seen in absolute or relative weights of the testes, prostate, ovaries, uterus, thyroid, adrenal and pituitary glands. <u>Histopathology:</u> No treatment-related histopathological lesions were seen in the testes, epididymides, prostate, ovaries, uterus, vagina, mammary, thyroid, adrenal or pituitary glands.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D C 20460

011565

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MAY 6 1995

MEMORANDUM

Subject: EPA ID # 067505-G: Ecto Flea & Tick Insecticide With IGR
for Adult Dogs and Puppies Older than 8 Weeks - Review of Domestic
Animal Safety Study (MRID # 43396408)

P.C. Nos.: 109701 & 29032
Tox. Chem. Nos.: 652BB
Submission No.: S475155
D.P. Barcode No.: D208877

From: Guruva B. Reddy, D.V.M., Ph.D. *6/2/94*
Section 4
Toxicology Branch I
Health Effects Division (7509C) *5/16/95*

To: Marion Johnson/Joseph Tavano
Project Manager 10
Registration Division (7505C)

Thru: John Doherty, Ph.D. *John Doherty 5/17/95*
Acting Section Head
Section 4, Toxicology Branch I
Health Effects Division (7509C) *6/5/95*

I. CONCLUSIONS:

The domestic animal safety study is inadequate and Unacceptable and does not satisfy the requirements, of a Series S 86-1 domestic animal safety study in adult dogs and puppies older than 8 weeks, because of violation of randomization procedures and inadequate number of animals; and lack of pertinent information such as bodyweight gain, food consumption etc., needed for evaluation of safety of the formulation were not collected or reported.

cc: Doherty

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II. ACTION REQUESTED:

ECTO Development Corporation, Excelsior Springs, MO., has submitted a domestic animal safety study in adult dogs and puppies older than 8 weeks, in support of registration of ECTO Flea & Tick Insecticide with IGR for the control of fleas, ticks and mosquitoes.

III. TOXICOLOGY BRANCH COMMENTS: The following study deficiencies were noted:

1. The study did not demonstrate a 3 - 5 fold safety factor between label usage rate and dermal reactions.
2. The animals selected for the study did not appear to be from a healthy stock. This is evidenced from the erythematous reactions in adults prior to application and presence of parvo virus, coccidial, bacterial and helminthic infections in puppies, which compromised study. Any or all treatments or prophylactic measures should be done during the acclimatization period.
3. Number of animals used in the study is inadequate. A minimum of 5/sex/age group, at 5 time the recommended dose level for twice the duration of intended use should be employed.
4. Data is lacking on bodyweight gains, food consumption, etc.. In the absence of which, safety of the treatments cannot be validated.
5. Dermal reactions in the vehicle treated were as severe as in the treated group. It appears the dermal reactions in this study were due to vehicle used in the formulation. Therefore, the registrant should consider changing vehicle for safer inactive ingredients.

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DATA MATRIX

Date: August 23, 2011			EPA Reg No./File Symbol 87825-R		Page 1 of 6
Applicant's/Registrant's Name & Address Virbac SA 1ere avenue 2065 M - LID F-06516 Carros, France			Product: Fipronil Technical		
Ingredient: Fipronil					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Product Chemistry Test Guidelines					
830.1550	Product Identity and Composition	48095240, 48449201	Virbac	OWN	
830.1600	Description of Materials Used	48095240	Virbac	OWN	
830.1620	Description of Production Process	48095239	Virbac	OWN	
830.1650	Description of Formulation Process	48095239	Virbac	OWN	
830.1670	Description of Formation of Impurities	48095240, 48449201	Virbac	OWN	
830.1700	Preliminary Analysis	48095241	Virbac	OWN	
830.1750	Certified Limits	48095240, 48449201	Virbac	OWN	
830.1800	Analytical Method	48095242	Virbac	OWN	
830.1900	Submittal of samples		Virbac	N/A	
830.6302	Color	48095240, 48095243	Virbac	OWN	
830.6303	Physical State	48095240, 48095243	Virbac	OWN	
830.6304	Odor	48095243	Virbac	OWN	
830.6313	Accelerated Storage Stability-Metal Ions	48095243	Virbac	OWN	
830.6314	Oxidation/reduction	48095239	Virbac	OWN	
830.6315	Flammability	48095239	Virbac	OWN	
830.6316	Explosibility	48095239	Virbac	NR	
830.6317	1 Yr. Storage Stability		Virbac	OWN	See note page 2
Signature 			Name and Title Jean-Pascal Marc Corporate Product Innovation Director		Date August 23, 2011

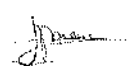


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DATA MATRIX

Date August 23, 2011			EPA Reg No./File Symbol 87825-R		Page 2 of 3
Applicant's/Registrant's Name & Address Virbac SA 1ere avenue 2065 M - LID F-06516 Carros, France			Product: Fipronil Technical		
Ingredient: Fipronil					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6318	Viscosity		Virbac	N/A	
830.6319	Miscibility		Virbac	N/A	Solid
830.6320	Corrosion characteristics		Virbac	OWN	See note page 2
830.6321	Dielectric breakdown voltage		Virbac	N/A	Waived
830.7000	pH	48095247	Virbac	OWN	
830.7200	Melting Point	48095249	Virbac	OWN	
830.7300	Density bulk density or specific gravity	48095250	Virbac	OWN	
830.7320	Particle Size		Virbac	N/A	
830.7050	UV/Visible Spectrum	48095248	Virbac	OWN	
830.7370	Dissociation constant	48095251	Virbac	OWN	
830.7520;830.7550; 830.7560 830.7570	Octanol/water partition coefficient	48095244	Virbac	OWN	
830.7840;830.7860	Solubility	48095245	Virbac	OWN	
830.7950	Vapor pressure	48095246	Virbac	OWN	
Signature 			Name and Title Jean-Pascal Marc Corporate Product Innovation Director		Date August 23, 2011

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Note: 830.6317 and 830.6320: Per Agency policy, storage stability and corrosion characteristics data are not required to be submitted unless specifically requested by the Agency. Virbac has initiated these studies and will submit the final reports if required when the studies are completed.




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DATA MATRIX

Date: August 23, 2011			EPA Reg No./File Symbol 87825-R		Page 3 of 6
Applicant's/Registrant's Name & Address Virbac SA 1ere avenue 2065 M - LID F-06516 Carros, France			Product: Fipronil Technical		
Ingredient: Fipronil					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
40 CFR 158.340 Toxicology Data Requirements					
870.1100	Acute oral toxicity	42918628; 43235401 43279706	BASF	OLD	
870.1200	Acute dermal toxicity	42918629	BASF	OLD	
870.1200	Acute dermal toxicity	43235402	BASF	OLD	
870.1300	Acute inhalation toxicity	42918631	BASF	OLD	
870.2400	Primary eye irritation	42918632	BASF	OLD	
870.2500	Primary dermal irritation	42918630	BASF	OLD	
870.2600	Dermal sensitization	42918634	BASF	OLD	
870.6100	Acute delayed neurotoxicity	42918635	BASF	OLD	
870.6100	Acute delayed neurotoxicity	43559501	BASF	OLD	
870.3100	90-day oral toxicity - rodent	42918643	BASF	OLD	
870.3150	90-day oral toxicity - nonrodent	42918642	BASF	OLD	
870.3200	21-day dermal toxicity	42918644	BASF	OLD	
870.3250	90-day dermal toxicity	DATA GAP	BASF	GAP	*See below
870.6100	90-day neurotoxicity - mammal	43291703	BASF	OLD	
81-8	Neurotoxicity to Rats by Acute Oral Administration	44431801	BASF	PAY	
Signature 			Name and Title Jean-Pascal Marc Corporate Product Innovation Director		Date August 23, 2011


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DATA MATRIX

Date August 23, 2011			EPA Reg No./File Symbol 87825-R	Page 4 of 6	
Applicant's/Registrant's Name & Address Virbac SA terre avenue 2065 M - LID F-06516 Carros, France			Product: Fipronil Technical		
Ingredient: Fipronil					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
40 CFR 158.340 Toxicology Data Requirements (Continued)					
84-2	Structural chromosomal aberration	42918680	BASF	OLD	
84-2	Structural chromosomal aberration	42918653	BASF	OLD	
84-2	Other genotoxic effects	42918651;42918653 43501703	BASF	OLD	
85-1/870.7485	General metabolism	42918655	BASF	OLD	
85-1/870.7485	General metabolism	43253701	BASF	PAY	
85-1/870.7485	General metabolism	43737308	BASF	OLD	
85-1/870.7485	General metabolism	42918654	BASF	OLD	
85-1/870.7485	General metabolism	42977904	BASF	OLD	
85-1/870.7485	General metabolism	43253701	BASF	OLD	
85-2/870.7600	Dermal penetration	43737308	BASF	PAY	
85-7/870.7600	Immunotoxicity	DATA GAP		GAP	*See below
40 CFR 158.490 Wildlife and Aquatic Organisms Data Requirements				OLD	
71-1/850.2100	Avian oral LD 50 - mallard or bobwhite	42918617 42918616	BASF	OLD	
72-1/850.1075	Freshwater fish LC 50 - rainbow or bluegill	42918624;42918673; 42918674;42977902 43279703;43291718	BASF	OLD OLD OLD	
Signature 			Name and Title Jean-Pascal Marc Corporate Product Innovation Director		Date August 23, 2011



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DATA MATRIX

Date: August 23, 2011			EPA Reg. No./File Symbol 87825-R		Page 5 of 6
Virbac SA 1ere avenue 2065 M - LID F-06516 Carros, France			Product: Fipronil Technical		
Ingredient: Fipronil					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
83-1/870.4100	Chronic feeding – rodent	42918648	BASF	OLD	
83-1/870.4100	Chronic feeding – nonrodent	42918645	BASF	OLD	
83-1/870.4100	Chronic feeding – nonrodent	43402802	BASF	PAY	
83-2/870.4200	Oncogenicity – mouse	42918649	BASF	OLD	
83-2/870.4200	Oncogenicity – mouse	43501702	BASF	PAY	
83-2/870.4200	Oncogenicity – rat	42918648	BASF	OLD	
83-3/870.3700	Teratogenicity – rabbit	42918646	BASF	OLD	
83-3/870.3700	Teratogenicity – rat	42977903	BASF	OLD	
83-3/870.3700	Teratogenicity – rat	44275001	BASF	PAY	
83-6/870.6300	Developmental neurotoxicity	44039002	BASF	PAY	
83-4/870.3800	Reproduction	42918647	BASF	OLD	
84-2/870.5100	Gene mutation	42918652	BASF	OLD	
84-2/870.5100	Gene mutation	42918679	BASF	OLD	
84-2/870.5100	Gene mutation	43291716	BASF	OLD	
84-2/870.5100	Gene mutation	43291717	BASF	OLD	
84-2/870.5100	Gene mutation	43291721	BASF	OLD	
84-2/870.5100	Gene mutation	43291722	BASF	OLD	
84-2/870.5100	Gene mutation	43401102	BASF	OLD	
Signature 			Name and Title Jean-Pascal Marc Corporate Product Innovation Director		Date August 23, 2011

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DATA MATRIX

Date: August 23, 2011			EPA Reg. No./File Symbol 87825-R		Page 6 of 6
Applicant's/Registrant's Name & Address Virbac SA 1ere avenue 2065 M - LID F-06516 Carros, France			Product: Fipronil Technical		
Ingredient: Fipronil					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	NOTE
72-2/850.1010	Acute LC 50 freshwater invertebrates (<i>Daphnia magna</i>)	42918625	BASF	OLD	
	Acute LC 50 freshwater invertebrates (<i>Daphnia magna</i>)	42918669	BASF	OLD	
	Acute LC 50 freshwater invertebrates (<i>Daphnia magna</i>)	42918671	BASF	OLD	
	Acute LC 50 freshwater invertebrates (<i>Daphnia magna</i>)	43291719	BASF	OLD	
835.2110	Hydrolysis	42977905	BASF	OLD	
40 CFR 158.390 Reentry Protection Data Requirements					
133-3	Dermal exposure - Fipronil	44433302	Merial	PAY	
133-4	Inhalation exposure - Fipronil	44433302	Merial	PAY	
132-1	Dislodgeable residue dissipation - Fipronil	44531203	Merial	PAY	
N/A	Dermal and inhalation exposure of commercial pet groomers (Spot) - Fipronil	44433303	Merial	PAY	
N/A	Analytical method for exposure studies - Fipronil	44433308	Merial	PAY	
Signature 			Name and Title Jean-Pascal Marc Corporate Product Innovation Director		August 23, 2011

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* Pursuant to 40 CFR 152.96 (c), Virbac hereby certifies that Virbac has no basis to believe that this requirement is not a data gap and, further, that Virbac has sent by certified mail to all companies on the current EPA Data Submitters List for fipronil a letter requesting that the company identify, within 60 days of receipt, any valid study that would fulfill this data requirement. Once this 60-day period expires, Virbac will update the Agency as to the information, if any, Virbac receives in response to this "data gap" letter.



48696900

December 20, 2011

Richard Gebken, PM 10
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Document Processing Desk (REGFEE)
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Subject: EFFIPRO® PLUS Topical Solution for Dogs (EPA File Symbol 2382-TBA);
New Product Application.

Dear Mr. Gebken,

Virbac Animal Health (Virbac AH, Inc. P. O. Box 162059, Ft. Worth, TX 76137, (Company Number 2382)) is hereby submitting an application to register the spot-on pesticide product EFFIPRO® PLUS Topical Solution for Dogs.

This product contains the active ingredients fipronil and pyriproxifen and is intended to control fleas, ticks, mosquitoes, and other pests on dogs only.

Pyriproxifen itself is registered alone and in combination with other active ingredients in numerous end use products for spot-on insect growth regulator use on dogs.

As indicated on Form 8570-34, Virbac is using the selective method to address applicable data requirements for this application pursuant to 40 CFR 152.90. Pursuant to 40 CFR 152.93, Offer to Pay letters are being sent to the submitters of data cited in Virbac's application that were originally submitted within the past 15 years.

Below is a list of the components included with this application:

1. Cover Letter;
2. Transmittal Document;
3. Application for Pesticide Form 8570-1;
4. Confidential Statement of Formula-2 Copies;
5. Data Matrix Form 8570-4; (EUP and TGAI);
6. Certification of Data Citation Form 8570-34;
7. Proposed Label - 5 copies;
8. 3 copies of bound PR 86-5 compliant study reports supporting registration;
9. Waiver Request for Acute Inhalation Study (attached to Cover Letter);
10. Letter of Self-certification of Child-Resistant Packaging;
11. Formulator's Exemption Form 8570-27; and
12. Copy of PRIA Check for category R-310 (\$4807).

Child-Resistant Packaging

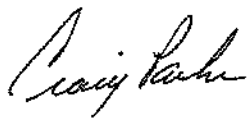
EFFIPRO® PLUS Topical Solution for Dogs and will be marketed in single dose unit applicators in packages of 1, 3, 6, and 36. These single dose applicators for the 0.67 ml, 1.34 ml, 2.68 ml, and 4.02 ml dose sizes have been previously tested, and CRP certification has been accepted by EPA. All relevant test data supporting self-certification have been reviewed and are cited in the attached Data Matrix. A self-certification letter is also attached.

PRIA Considerations

After reviewing the Agency's PRIA category interpretations, we believe that the R-310 PRIA category and a 6 month review period is appropriate for this product. Consequently, please find a copy of one previously submitted check in the amount of \$4807 to cover the PRIA fee.

Should you have any questions about this application package, please do not hesitate to contact me via telephone at 682-647-3576 or via e-mail at craig.parks@virbacus.com.

Sincerely,



Craig Parks, MS, DVM
Vice President, Research & Development
Virbac Animal Health, Inc.

Attachments

12/20/2011

TRANSMITTAL DOCUMENT**NAME AND ADDRESS OF SUBMITTER:**

Virbac, Inc. (EPA Company Number 2382)

P.O. Box 162059

Fort Worth, TX 76161

REGULATORY ACTION SUPPORTED BY THIS PACKAGE:

This submission is an application to register an end use pro namely EFFIPRO® PLUS Topical Solution for Dogs. Effipro® EFFIPRO® PLUS Topical Solution for Dogs contains the active ingredients Fipronil and Pyriproxyfen.

SUBMITTAL DATE:

December 20, 2011

Volume	Study Title	MRID No.
1	Administrative Materials Effipro® Plus Topical Solution for Dogs	
	<i>Group A Product Chemistry</i>	
2	OPPTS 830.1550, 830.1750, 830.1600, 830.1620, 830.1650, 830.1670 EFFIPRO® PLUS Topical Solution for Dogs	48696901
	<i>Group B Product Chemistry</i>	
3	OPPTS 830.6302, 830.6303, 830.6304 Determination of the Physico-Chemical Property "Appearance (Color, Physical State and Odor)"	48696902
4	OPPTS 830.6314 Determination of Oxidation / Reduction (Chemical Incompatibility)	48696903
5	OPPTS 830.6315 Determination of the Physico-Chemical Property "Flash Point"	48696904
6	OPPTS 830.7000 Determination of the Physico-Chemical Property "pH"	48696905
7	OPPTS 830.7100 Determination of Physico-Chemical Property "Viscosity"	48696906
8	OPPTS 830.7300 Determination of the Physico-Chemical Property "Relative Density"	48696907

Volume	Study Title	MRID No.
9	OPPTS 830.1700, 830.1800 Quantification of the Active Ingredients Fipronil and Pyriproxyfen in Five Batches by Validated Methods	48696908
10	OPPTS 830.1800 Enforcement Analytical Method – Quantification of the Active Ingredients Fipronil and Pyriproxyfen	48696909
	<i>Acute Toxicity</i>	
11	OPPTS 870.1100 Acute Oral Toxicity Study in Rats – Up-and-Down-Procedure	48696910
12	OPPTS 870.1200 Acute Dermal Toxicity Study in Rats	48696911
13	OPPTS 870.2400 Acute Eye Irritation Study in Rabbits	48696912
14	OPPTS 870.2500 Acute Dermal Irritation Study in Rabbits	48696913
15	OPPTS 870.2600 Contact Hypersensitivity in Albino Guinea Pigs, Buehler Test	48696914
	<i>Product Performance</i>	
16	OPPTS 810.3300 Summary of Efficacy Data for EFFIPRO® PLUS Topical Solution for Dogs	48696915
	<i>Product Safety</i>	
17	OPPTS 870.7200 Summary of Companion Animal Safety Data for EFFIPRO® PLUS Topical Solution for Dogs	48696916

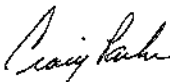
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DATA MATRIX

Date: December 20, 2011			EPA Reg. No./File Symbol 2382-TBA	Page 1 of 9	
Applicant's/Registrant's Name & Address Virbac AH, Inc. PO Box 162059 Fort Worth TX 76161			Product: EFFIPRO® PLUS TOPICAL SOLUTION FOR DOGS		
Ingredient: Fipronil, Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Product Chemistry Test Guidelines					
830.1550	Product Identity and Composition	New Submission	Virbac AH, Inc.	OWN	
830.1600	Description of Materials Used	New Submission	Virbac AH, Inc.	OWN	
830.1620	Description of Production Process	New Submission	Virbac AH, Inc.	OWN	
830.1650	Description of Formulation Process	New Submission	Virbac AH, Inc.	OWN	
830.1670	Description of Formation of Impurities	New Submission	Virbac AH, Inc.	OWN	
830.1700	5-Batch Analysis	New Submission	Virbac AH, Inc.	OWN	
830.1750	Certified Limits	New Submission	Virbac AH, Inc.	OWN	
830.1800	Analytical Method	New Submission	Virbac AH, Inc.	OWN	
830.6302	Color	New Submission	Virbac AH, Inc.	OWN	
830.6303	Physical State	New Submission	Virbac AH, Inc.	OWN	
830.6304	Odor	New Submission	Virbac AH, Inc.	OWN	
830.6313	Metal Stability		Virbac AH, Inc.	NR	
830.6314	Oxidation/reduction	New Submission	Virbac AH, Inc.	OWN	
830.6315	Flammability	New Submission	Virbac AH, Inc.	OWN	
830.6316	Explosibility		Virbac AH, Inc.	NR	
830.6317	Storage stability	To be conducted	Virbac AH, Inc.	OWN	
Signature 			Name and Title Craig Parks Vice President, Research & Development		Date December 20, 2011

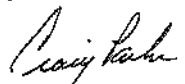
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DATA MATRIX

Date December 20, 2011			EPA Reg. No./File Symbol 2382-rBA		Page 2 of 9
Applicant's/Registrant's Name & Address Virbac AH, Inc. PO Box 162059 Fon Worth TX 76161			Product: EFFIPRO® PLUS TOPICAL SOLUTION FOR DOGS		
Ingredient: Fipronil, Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7100	Viscosity	New Submission	Virbac AH, Inc.	OWN	
830.6319	Miscibility		Virbac AH, Inc.	NR	
830.6320	Corrosion characteristics	To be conducted	Virbac AH, Inc.	OWN	
830.6321	Dielectric breakdown voltage		Virbac AH, Inc.	NR	
830.7000	pH	New Submission	Virbac AH, Inc.	OWN	
830.7300	Density, bulk density, or specific gravity	New Submission	Virbac AH, Inc.	OWN	
830.7320	Particle Size distribution		Virbac AH, Inc.	NR	
40 CFR 158.340 Toxicology Data Requirements					
870.1100	Acute oral toxicity	New Submission	Virbac AH, Inc.	OWN	
870.1200	Acute dermal toxicity	New Submission	Virbac AH, Inc.	OWN	
870.1300	Acute inhalation toxicity	Waiver requested	Virbac AH, Inc.		
870.2400	Primary eye irritation	New Submission	Virbac AH, Inc.	OWN	
870.2500	Primary dermal irritation	New Submission	Virbac AH, Inc.	OWN	
870.2600	Dermal sensitization	New Submission	Virbac AH, Inc.	OWN	
Signature 			Name and Title Craig Parks Vice President, Research & Development		Date December 20, 2011

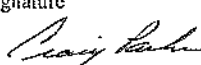
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DATA MATRIX

Date: December 20, 2011		EPA Reg. No./File Symbol: 2382-TBA		Page 3 of 9	
Applicant's/Registrant's Name & Address Virbac AH, Inc PO Box 162059 Fort Worth TX 76161		Product: EFFIPRO® PLUS TOPICAL SOLUTION FOR DOGS			
Ingredient: Fipronil, Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Efficacy and Safety Data					
870.7200	Dog safety	43444905	Merial	OLD	
870.7200	Dog safety	43577711	Merial	OLD	
870.7200	Dog safety	43863802	Merial	OLD	
870.7200	Dog safety	43121110	Merial	OLD	
870.7200	Dog safety	43121111	Merial	OLD	
870.7200	Dog safety	43620507	Merial	PAY	
870.7200	Dog safety	43396408	Ecto Development Corporation	OLD	
870.7200	Dog safety	43612601	Ecto Development Corporation	OLD	
870.7200	Dog safety	44900902	Virbac AH, Inc.	OWN	
870.7200	Dog safety	44900903	Virbac AH, Inc.	OWN	
870.7200	Dog safety	42178309	Sumitomo Chemical Company, Ltd.	OLD	
870.7200	Dog safety	New submission	Virbac AH, Inc.	OWN	
810.3300	Efficacy	43121114	Merial	OLD	
810.3300	Efficacy	43121115	Merial	OLD	
810.3300	Efficacy	43121116	Merial	OLD	
810.3300	Efficacy	43121117	Merial	OLD	
810.3300	Efficacy	43121118	Merial	OLD	
810.3300	Efficacy	43121119	Merial	OLD	
810.3300	Efficacy	43121120	Merial	OLD	
Signature 			Name and Title Craig Parks Vice President, Research & Development		Date December 20, 2011

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DATA MATRIX

Date: December 20, 2011			EPA Reg. No./File Symbol 2382-TBA	Page 4 of 9	
Applicant's/Registrant's Name & Address Virbac AH, Inc PO Box 162059 Fort Worth TX 76161			Product: EFFIPRO® PLUS TOPICAL SOLUTION FOR DOGS		
Ingredient: Fipronil, Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Efficacy and Safety Data					
810.3300	Efficacy	43121121	Merial	OLD	
810.3300	Efficacy	43121122	Merial	OLD	
810.3300	Efficacy	43444901	Merial	OLD	
810.3300	Efficacy	43577701	Merial	OLD	
810.3300	Efficacy	43577712	Merial	OLD	
810.3300	Efficacy	43577713	Merial	OLD	
810.3300	Efficacy	43951701	Merial	OLD	
810.3300	Efficacy	44088901	Merial	OLD	
810.3300	Efficacy	46006002	Wellmark International	PUBL	
810.3300	Efficacy	44900904	Virbac AH, Inc.	OWN	
810.3300	Efficacy	45020601	Virbac AH, Inc.	OWN	
810.3300	Efficacy	Pending; submitted with Effipro Plus Cat Application		OWN	
810.3300	Efficacy	New submission		OWN	
Signature 			Name and Title Craig Parks Vice President, Research & Development		Date December 20, 2011

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DATA MATRIX

Date December 20, 2011	EPA Reg. No./File Symbol 2382-TBA	Page 5 of 9
Applicant's/Registrant's Name & Address Virbac AH, Inc PO Box 162059 Fort Worth TX 76161	Product: EFFIPRO® PLUS TOPICAL SOLUTION FOR DOGS	

Ingredient: Fipronil, Pyriproxyfen

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
810.3300	Efficacy	44942011	Merial	PAY	
810.3300	Efficacy	44942106	Merial	PAY	
810.3300	Efficacy	45612701	Merial	PAY	
810.3300	Efficacy	45618501	Merial	PAY	
810.3300	Efficacy	45620501	Merial	PAY	
810.3300	Efficacy	45620502	Merial	PAY	
810.3300	Efficacy	45620503	Merial	PAY	
810.3300	Efficacy	45620504	Merial	PAY	
810.3300	Efficacy	45620505	Merial	PAY	
810.3300	Efficacy	45620506	Merial	PAY	
810.3300	Efficacy	45628101	Merial	PAY	
810.3300	Efficacy	45628102	Merial	PAY	
810.3300	Efficacy	45628103	Merial	PAY	
810.3300	Efficacy	45628104	Merial	PAY	
810.3300	Efficacy	45628105	Merial	PAY	
810.3300	Efficacy	45628201	Merial	PAY	
810.3300	Efficacy	45866901	Merial	PAY	
810.3300	Efficacy	45866902	Merial	PAY	
810.3300	Efficacy	46019201	Merial	PAY	
810.3300	Efficacy	46019202	Merial	PAY	

Signature

Name and Title
Craig Parks
Vice President, Research & Development

Date
December
20, 2011

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DATA MATRIX

Date: December 20, 2011			EPA Reg. No./File Symbol 2382-TBA		Page 6 of 9
Applicant's/Registrant's Name & Address Virbac AH, Inc PO Box 162059 Fort Worth TX 76161			Product: EFFIPRO® PLUS TOPICAL SOLUTION FOR DOGS		
Ingredient: Fipronil, Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Child Resistant Packaging					
40 CFR 157	Evaluation of the 3 ml Applicator Tube with 1.34 ml water, 1 applicator tube test for Child-Resistant Effectiveness	48095221	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 3 ml Applicator Tube with 1.34 ml water, 6 applicators tube test for Child-Resistant Effectiveness	48095222	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 3 ml Applicator Tube with 1.34 ml water, 36 applicators tube test for Child-Resistant Effectiveness	48095223	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 3 ml Applicator Tube with 1.34 ml water, 1 applicator tube test for Senior-Use Effectiveness	48095224	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 3 ml Applicator Tube with 1.34 ml water, 6 applicators tube test for Senior-Use Effectiveness	48095225	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 3 ml Applicator Tube with 1.34 ml water, 36 applicators tube test for Senior-Use Effectiveness	48095226	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 3 ml Applicator Tube with 2.68ml water, 1 applicator tube test for Child-Resistant Effectiveness	48095227	Virbac AH, Inc.	OWN	
Signature 			Name and Title Craig Parks Vice President, Research & Development		Date December 20, 2011

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DATA MATRIX

Date: December 16, 2011		EPA Reg. No./File Symbol 2382-TBA		Page 7 of 9	
Applicant's/Registrant's Name & Address Virbac AH, Inc PO Box 162059 Fort Worth TX 76161		Product: EFFIPRO® PLUS TOPICAL SOLUTION FOR DOGS			
Ingredient: Fipronil, Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
40 CFR 157	Evaluation of the 3 ml Applicator Tube with 2.68 ml water, 6 applicators tube test for Child-Resistant Effectiveness	48095228	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 3 ml Applicator Tube with 2.68 ml water, 36 applicators tube test for Child-Resistant Effectiveness	48095229	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 3 ml Applicator Tube with 2.68 ml water, 1 applicator tube test for Senior-Use Effectiveness	48095230	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 3 ml Applicator Tube with 2.68 ml water, 6 applicators tube test for Senior-Use Effectiveness	48095231	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 3 ml Applicator Tube with 2.68 ml water, 36 applicators tube test for Senior-Use Effectiveness	48095232	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 6 ml Applicator Tube with 4.02 ml water, 1 applicator tube test for Child-Resistant Effectiveness	48095233	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 6 ml Applicator Tube with 4.02 ml water, 6 applicators tube test for Child-Resistant Effectiveness	48095234	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 6 ml Applicator Tube with 4.02 ml water, 36 applicators tube test for Child-Resistant Effectiveness	48095235	Virbac AH, Inc.	OWN	
Signature 			Name and Title Craig Parks Vice President, Research & Development		Date December 20, 2011

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DATA MATRIX

Date: December 20, 2011			EPA Reg. No./File Symbol 2382-TBA		Page 8 of 9
Applicant's/Registrant's Name & Address Virbac AH, Inc PO Box 162059 Fort Worth TX 76161			Product: EFFIPRO® PLUS TOPICAL SOLUTION FOR DOGS		
Ingredient: Fipronil, Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
40 CFR 157	Evaluation of the 1ml applicator tube with 0.67 ml water, 1 applicator tube test for Child-Resistant Effectiveness	48410001	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 1ml applicator tube with 0.67 ml water, 1 applicator tube test for Senior-Use Effectiveness	48410002	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 1ml applicator tube with 0.67 ml water, 6 applicator tube test for Child-Resistant Effectiveness	48410003	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 1ml applicator tube with 0.67 ml water, 6 applicator tube test for Senior-Use Effectiveness	48410004	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 1ml applicator tube with 0.67 ml water, 36 applicator tube test for Child-Resistant Effectiveness	48410005	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 1ml applicator tube with 0.67 ml water, 36 applicator tube test for Senior-Use Effectiveness	48410006	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 1ml applicator tube with 0.67 ml water, 3 applicator tube test for Child-Resistant Effectiveness	48410007	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 1ml applicator tube with 0.67 ml water, 3 applicator tube test for Senior-Use Effectiveness	48410008	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 3ml applicator tube with 1.34 ml water, 3 applicator tube test for Child-Resistant Effectiveness	48410009	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 3ml applicator tube with 1.34 ml water, 3 applicator tube test for Senior-Use Effectiveness	48410010	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 3ml applicator tube with 2.68 ml water, 3 applicator tube test for Child-Resistant Effectiveness	48410011	Virbac AH, Inc.	OWN	
Signature 			Name and Title Craig Parks Vice President, Research & Development		Date December 20, 2011

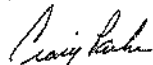
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Date December 20, 2011			EPA Reg. No./File Symbol 2382-TBA		Page 9 of 9
Applicant's/Registrant's Name & Address Virbac AH, Inc PO Box 162059 Fort Worth TX 76161			Product: EFFIPRO® PLUS TOPICAL SOLUTION FOR DOGS		
Ingredient: Fipronil, Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
40 CFR 157	Evaluation of the 3ml applicator tube with 2.68 ml water, 3 applicator tube test for Senior-Use Effectiveness	48410012	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 1ml applicator tube with 4.02 ml water, 3 applicator tube test for Child-Resistant Effectiveness	48410013	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 1ml applicator tube with 4.02 ml water, 3 applicator tube test for Senior-Use Effectiveness	48410014	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 3ml applicator tube with 2.68 ml water, 1 applicator tube test for Senior-Use Effectiveness	48410015	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 3ml applicator tube with 2.68 ml water, 36 applicator tube test for Senior-Use Effectiveness	48410016	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 6ml applicator tube with 4.02 ml water, 6 applicator tube test for Senior-Use Effectiveness	48410017	Virbac AH, Inc.	OWN	
Signature 			Name and Title Craig Parks Vice President, Research & Development		Date December 20, 2011




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DATA MATRIX

Date: August 23, 2011		EPA Reg No./File Symbol 87825-R		Page 1 of 6	
Applicant's/Registrant's Name & Address Virbac SA 1ere avenue 2065 M - LID F-06516 Carrns, France		Product: Fipronil Technical			
Ingredient: Fipronil					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Product Chemistry Test Guidelines					
830.1550	Product Identity and Composition	48095240, 48449201	Virbac	OWN	
830.1600	Description of Materials Used	48095240	Virbac	OWN	
830.1620	Description of Production Process	48095239	Virbac	OWN	
830.1650	Description of Formulation Process	48095239	Virbac	OWN	
830.1670	Description of Formation of Impurities	48095240, 48449201	Virbac	OWN	
830.1700	Preliminary Analysis	48095241	Virbac	OWN	
830.1750	Certified Limits	48095240, 48449201	Virbac	OWN	
830.1800	Analytical Method	48095242	Virbac	OWN	
830.1900	Submittal of samples		Virbac	N/A	
830.6302	Color	48095240, 48095243	Virbac	OWN	
830.6303	Physical State	48095240, 48095243	Virbac	OWN	
830.6304	Odor	48095243	Virbac	OWN	
830.6313	Accelerated Storage Stability-Metal Ions	48095243	Virbac	OWN	
830.6314	Oxidation/reduction	48095239	Virbac	OWN	
830.6315	Flammability	48095239	Virbac	OWN	
830.6316	Explosibility	48095239	Virbac	NR	
830.6317	1 Yr. Storage Stability		Virbac	OWN	See note page 2
Signature 			Name and Title Jean-Pascal Marc Corporate Product Innovation Director		Date August 23, 2011


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DATA MATRIX

Date August 23, 2011			EPA Reg No./File Symbol 87825-R		Page 2 of 6
Applicant's/Registrant's Name & Address Virbac SA tere avenue 2065 M - LID F-06516 Carros, France			Product: Fipronil Technical		
Ingredient: Fipronil					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6318	Viscosity		Virbac	N/A	
830.6319	Miscibility		Virbac	N/A	Solid
830.6320	Corrosion characteristics		Virbac	OWN	See note page 2
830.6321	Dielectric breakdown voltage		Virbac	N/A	Waived
830.7000	pH	48095247	Virbac	OWN	
830.7200	Melting Point	48095249	Virbac	OWN	
830.7300	Density bulk density or specific gravity	48095250	Virbac	OWN	
830.7320	Particle Size		Virbac	N/A	
830.7050	UV/Visible Spectrum	48095248	Virbac	OWN	
830.7370	Dissociation constant	48095251	Virbac	OWN	
830.7520;830.7550; 830.7560 830.7570	Octanol/water partition coefficient	48095244	Virbac	OWN	
830.7840;830.7860	Solubility	48095245	Virbac	OWN	
830.7950	Vapor pressure	48095246	Virbac	OWN	
Signature 			Name and Title Jean-Pascal Mure Corporate Product Innovation Director		Date August 23, 2011

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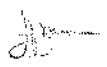
Note: 830.6317 and 830.6320: Per Agency policy, storage stability and corrosion characteristics data are not required to be submitted unless specifically requested by the Agency. Virbac has initiated these studies and will submit the final reports if required when the studies are completed.

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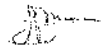
Date: August 23, 2011		EPA Reg No./File Symbol 87825-R		Page 3 of 6	
Applicant's/Registrant's Name & Address Virbac SA 1ere avenue 2065 M - LID F-06516 Carros, France		Product: Fipronil Technical			
Ingredient: Fipronil					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
40 CFR 158.340 Toxicology Data Requirements					
870.1100	Acute oral toxicity	42918628; 43235401 43279706	BASF	OLD	
870.1200	Acute dermal toxicity	42918629	BASF	OLD	
870.1200	Acute dermal toxicity	43235402	BASF	OLD	
870.1300	Acute inhalation toxicity	42918631	BASF	OLD	
870.2400	Primary eye irritation	42918632	BASF	OLD	
870.2500	Primary dermal irritation	42918630	BASF	OLD	
870.2600	Dermal sensitization	42918634	BASF	OLD	
870.6100	Acute delayed neurotoxicity	42918635	BASF	OLD	
870.6100	Acute delayed neurotoxicity	43559501	BASF	OLD	
870.3100	90-day oral toxicity – rodent	42918643	BASF	OLD	
870.3150	90-day oral toxicity – nonrodent	42918642	BASF	OLD	
870.3200	21-day dermal toxicity	42918644	BASF	OLD	
870.3250	90-day dermal toxicity	DATA GAP	BASF	GAP	*See below
870.6100	90-day neurotoxicity – mammal	43291703	BASF	OLD	
81-8	Neurotoxicity to Rats by Acute Oral Administration	44431801	BASF	PAY	
Signature 			Name and Title Jean-Pascal Marc Corporate Product Innovation Director		Date August 23, 2011

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DATA MATRIX

Date: August 23, 2011		EPA Reg No./File Symbol: 87825-R		Page 4 of 6	
Applicant's/Registrant's Name & Address Virbac SA Iere avenue 2065 M - LID F-06516 Carros, France		Product: Fipronil Technical			
Ingredient: Fipronil					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
40 CFR 158.340 Toxicology Data Requirements (Continued)					
84-2	Structural chromosomal aberration	42918680	BASF	OLD	
84-2	Structural chromosomal aberration	42918653	BASF	OLD	
84-2	Other genotoxic effects	42918651;42918653 43501703	BASF	OLD	
85-1/870.7485	General metabolism	42918655	BASF	OLD	
85-1/870.7485	General metabolism	43253701	BASF	PAY	
85-1/870.7485	General metabolism	43737308	BASF	OLD	
85-1/870.7485	General metabolism	42918654	BASF	OLD	
85-1/870.7485	General metabolism	42977904	BASF	OLD	
85-1/870.7485	General metabolism	43253701	BASF	OLD	
85-2/870.7600	Dermal penetration	43737308	BASF	PAY	
85-7/870.7600	Immunotoxicity	DATA GAP		GAP	*See below
40 CFR 158.490 Wildlife and Aquatic Organisms Data Requirements					
71-1/850.2100	Avian oral LD 50 - mallard or bobwhite	42918617 42918616	BASF	OLD	
72-1/850.1075	Freshwater fish LC 50 - rainbow or bluegill	42918624;42918673; 42918674;42977902 43279703;43291718	BASF	OLD OLD OLD	
Signature 			Name and Title Jean-Pascal Marc Corporate Product Innovation Director		Date August 23, 2011

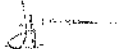
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Ingredient: Fipronil					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
83-1/870.4100	Chronic feeding – rodent	42918648	BASF	OLD	
83-1/870.4100	Chronic feeding – nonrodent	42918645	BASF	OLD	
83-1/870.4100	Chronic feeding – nonrodent	43402802	BASF	PAY	
83-2/870.4200	Oncogenicity – mouse	42918649	BASF	OLD	
83-2/870.4200	Oncogenicity – mouse	43501702	BASF	PAY	
83-2/870.4200	Oncogenicity – rat	42918648	BASF	OLD	
83-3/870.3700	Teratogenicity – rabbit	42918646	BASF	OLD	
83-3/870.3700	Teratogenicity – rat	42977903	BASF	OLD	
83-3/870.3700	Teratogenicity – rat	44275001	BASF	PAY	
83-6/870.6300	Developmental neurotoxicity	44039002	BASF	PAY	
83-4/870.3800	Reproduction	42918647	BASF	OLD	
84-2/870.5100	Gene mutation	42918652	BASF	OLD	
84-2/870.5100	Gene mutation	42918679	BASF	OLD	
84-2/870.5100	Gene mutation	43291716	BASF	OLD	
84-2/870.5100	Gene mutation	43291717	BASF	OLD	
84-2/870.5100	Gene mutation	43291721	BASF	OLD	
84-2/870.5100	Gene mutation	43291722	BASF	OLD	
84-2/870.5100	Gene mutation	43401102	BASF	OLD	
Signature 			Name and Title Jean-Pascal Marc Corporate Product Innovation Director		Date August 23, 2011

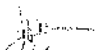
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Ingredient: Fipronil					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
72-2/850.1010	Acute LC 50 freshwater invertebrates (<i>Daphnia magna</i>)	42918625	BASF	OLD	
	Acute LC 50 freshwater invertebrates (<i>Daphnia magna</i>)	42918669	BASF	OLD	
	Acute LC 50 freshwater invertebrates (<i>Daphnia magna</i>)	42918671	BASF	OLD	
	Acute LC 50 freshwater invertebrates (<i>Daphnia magna</i>)	43291719	BASF	OLD	
835.2110	Hydrolysis	42977905	BASF	OLD	
40 CFR 158.390 Reentry Protection Data Requirements					
133-3	Dermal exposure - Fipronil	44433302	Merial	PAY	
133-4	Inhalation exposure - Fipronil	44433302	Merial	PAY	
132-1	Dislodgeable residue dissipation - Fipronil	44531203	Merial	PAY	
N/A	Dermal and inhalation exposure of commercial pet groomers (Spot) - Fipronil	44433303	Merial	PAY	
N/A	Analytical method for exposure studies - Fipronil	44433308	Merial	PAY	
Signature 			Name and Title Jean-Pascal Marc Corporate Product Innovation Director		August 23, 2011

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* Pursuant to 40 CFR 152.96 (c), Virbac hereby certifies that Virbac has no basis to believe that this requirement is not a data gap and, further, that Virbac has sent by certified mail to all companies on the current EPA Data Submitters List for fipronil a letter requesting that the company identify, within 60 days of receipt, any valid study that would fulfill this data requirement. Once this 60-day period expires, Virbac will update the Agency as to the information, if any, Virbac receives in response to this "data gap" letter.

Explore Registrations					
Reg Number:	2382 RIO	Reg. Type:	Product Registration - Section 3	Status:	Under Review (20-Dec-2011)
Name:	EFFIPRO PLUS TOPICAL SOLUTION FOR DOGS			<View Registration Details>	
(No New Receipts)					
S	Submission Type	OPP Rec'd Date	Resubmission	Description	
<div> <div>...Decisions...</div> <div> <div>Data Requirements</div> <div>D: Pending; 459013; 2382-RIO; R310; NEW PRO.</div> <div>75-Day Letters</div> <div>S: 911475 2/9/2012; New Registration; 2:3</div> <div>S: 908748 12/20/2011; New Registration; 2:</div> </div> </div>		<div> <div>S: 911475 Reg #: 2382-RIO</div> <div>Submission Type: New Registration</div> <div>Resubmission?: <input checked="" type="radio"/> Yes <input type="radio"/> No E-Sub #: </div> <div>Decision #: 459013; R310; NEW PRODUCT; NON-FAST TRACK (INCLUDES</div> <div>Submitter Company: VIRBAC AH, INC.</div> <div>Application Date: 06-Feb-2012</div> <div>OPP Received Date: 08-Feb-2012 Date Sent to Risk manager: 10-Feb-2012</div> <div>Studies Included?: <input type="radio"/> Yes <input checked="" type="radio"/> No Fast Track?: <input type="radio"/> Yes <input checked="" type="radio"/> No</div> <div>Form A Signed?: <input type="radio"/> Yes <input type="radio"/> No <input checked="" type="radio"/> None Date: </div> <div>Form B Signed?: <input type="radio"/> Yes <input type="radio"/> No <input checked="" type="radio"/> None Date: </div> <div>Reviewer: Akinlosotu, Bonaventure</div> <div>Received DT: Editable Due DT: </div> <div>Submission Due DT: 10-Jul-2012 Response: D, 08-Feb-2012</div> <div>Priority Weight: Priority Points: </div> <div>Comments: Submission of addition of citations to the Data Matrix</div> </div>			

• Resubmitted Revised Data Matrix per Reg (CRP) request to add "mems for SAME testing".




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DATA MATRIX

Date: August 23, 2011			EPA Reg No./File Symbol 87825-R		Page 1 of 6
Applicant's/Registrant's Name & Address Virbac SA 1ere avenue 2065 M - LID F-06516 Carros, France			Product: Fipronil Technical		
Ingredient: Fipronil					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Product Chemistry Test Guidelines					
830.1550	Product Identity and Composition	48095240, 48449201	Virbac	OWN	
830.1600	Description of Materials Used	48095240	Virbac	OWN	
830.1620	Description of Production Process	48095239	Virbac	OWN	
830.1650	Description of Formulation Process	48095239	Virbac	OWN	
830.1670	Description of Formation of Impurities	48095240, 48449201	Virbac	OWN	
830.1700	Preliminary Analysis	48095241	Virbac	OWN	
830.1750	Certified Limits	48095240, 48449201	Virbac	OWN	
830.1800	Analytical Method	48095242	Virbac	OWN	
830.1900	Submittal of samples		Virbac	N/A	
830.6302	Color	48095240, 48095243	Virbac	OWN	
830.6303	Physical State	48095240, 48095243	Virbac	OWN	
830.6304	Odor	48095243	Virbac	OWN	
830.6313	Accelerated Storage Stability-Metal Ions	48095243	Virbac	OWN	
830.6314	Oxidation/reduction	48095239	Virbac	OWN	
830.6315	Flammability	48095239	Virbac	OWN	
830.6316	Explosibility	48095239	Virbac	NR	
830.6317	1 Yr. Storage Stability		Virbac	OWN	See note page 2
Signature 			Name and Title Jean-Pascal Marc Corporate Product Innovation Director		Date August 23, 2011

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Date August 23, 2011			EPA Reg No./File Symbol 87825-R		Page 2 of 6
Applicant's/Registrant's Name & Address Virbac SA 1 rue avenue 2065 M - LID F-06516 Carros, France			Product: Fipronil Technical		
Ingredient: Fipronil					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6318	Viscosity		Virbac	N/A	
830.6319	Miscibility		Virbac	N/A	Solid
830.6320	Corrosion characteristics		Virbac	OWN	See note page 2
830.6321	Dielectric breakdown voltage		Virbac	N/A	Waived
830.7000	pH	48095247	Virbac	OWN	
830.7200	Melting Point	48095249	Virbac	OWN	
830.7300	Density bulk density or specific gravity	48095250	Virbac	OWN	
830.7320	Particle Size		Virbac	N/A	
830.7050	UV/Visible Spectrum	48095248	Virbac	OWN	
830.7370	Dissociation constant	48095251	Virbac	OWN	
830.7520;830.7550; 830.7560 830.7570	Octanol/water partition coefficient	48095244	Virbac	OWN	
830.7840;830.7860	Solubility	48095245	Virbac	OWN	
830.7950	Vapor pressure	48095246	Virbac	OWN	
Signature 			Name and Title Jean-Pascal Marc Corporate Product Innovation Director		Date August 23, 2011

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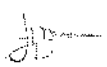
Note: 830.6317 and 830.6320: Per Agency policy, storage stability and corrosion characteristics data are not required to be submitted unless specifically requested by the Agency. Virbac has initiated these studies and will submit the final reports if required when the studies are completed.

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Applicant's/Registrant's Name & Address Virbac SA 1ere avenue 2065 M - LID F-06516 Carros, France			Product: Fipronil Technical		
Ingredient: Fipronil					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
40 CFR 158.340 Toxicology Data Requirements					
870.1100	Acute oral toxicity	42918628; 43235401 43279706	BASF	OLD	
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870.1300	Acute inhalation toxicity	42918631	BASF	OLD	
870.2400	Primary eye irritation	42918632	BASF	OLD	
870.2500	Primary dermal irritation	42918630	BASF	OLD	
870.2600	Dermal sensitization	42918634	BASF	OLD	
870.6100	Acute delayed neurotoxicity	42918635	BASF	OLD	
870.6100	Acute delayed neurotoxicity	43559501	BASF	OLD	
870.3100	90-day oral toxicity - rodent	42918643	BASF	OLD	
870.3150	90-day oral toxicity - nonrodent	42918642	BASF	OLD	
870.3200	21-day dermal toxicity	42918644	BASF	OLD	
870.3250	90-day dermal toxicity	DATA GAP	BASF	GAP	*See below
870.6100	90-day neurotoxicity - mammal	43291703	BASF	OLD	
81-8	Neurotoxicity to Rats by Acute Oral Administration	44431801	BASF	PAY	
Signature 			Name and Title Jean-Pascal Marc Corporate Product Innovation Director		Date August 23, 2011

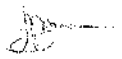
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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
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85-1/870.7485	General metabolism	43253701	BASF	PAY	
85-1/870.7485	General metabolism	43737308	BASF	OLD	
85-1/870.7485	General metabolism	42918654	BASF	OLD	
85-1/870.7485	General metabolism	42977904	BASF	OLD	
85-1/870.7485	General metabolism	43253701	BASF	OLD	
85-2/870.7600	Dermal penetration	43737308	BASF	PAY	
85-7/870.7600	Immunotoxicity	DATA GAP		GAP	*See below
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71-1/850.2100	Avian oral LD 50 - mallard or bobwhite	42918617 42918616	BASF	OLD	
72-1/850.1075	Freshwater fish LC 50 - rainbow or bluegill	42918624;42918673; 42918674;42977902 43279703;43291718	BASF	OLD OLD OLD	
Signature 			Name and Title Jean-Pascal Mare Corporate Product Innovation Director		Date August 23, 2011

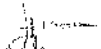
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83-2/870.4200	Oncogenicity – mouse	43501702	BASF	PAY	
83-2/870.4200	Oncogenicity – rat	42918648	BASF	OLD	
83-3/870.3700	Teratogenicity – rabbit	42918646	BASF	OLD	
83-3/870.3700	Teratogenicity – rat	42977903	BASF	OLD	
83-3/870.3700	Teratogenicity – rat	44275001	BASF	PAY	
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83-4/870.3800	Reproduction	42918647	BASF	OLD	
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84-2/870.5100	Gene mutation	43291716	BASF	OLD	
84-2/870.5100	Gene mutation	43291717	BASF	OLD	
84-2/870.5100	Gene mutation	43291721	BASF	OLD	
84-2/870.5100	Gene mutation	43291722	BASF	OLD	
84-2/870.5100	Gene mutation	43401102	BASF	OLD	
Signature 			Name and Title Jean-Pascal Marc Corporate Product Innovation Director		Date August 23, 2011


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N/A	Dermal and inhalation exposure of commercial pet groomers (Spot) - Fipronil	44433303	Merial	PAY	
N/A	Analytical method for exposure studies - Fipronil	44433308	Merial	PAY	
Signature 			Name and Title Jean-Pascal Marc Corporate Product Innovation Director		August 23, 2011

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* Pursuant to 40 CFR 152.96 (c), Virbac hereby certifies that Virbac has no basis to believe that this requirement is not a data gap and, further, that Virbac has sent by certified mail to all companies on the current EPA Data Submitters List for fipronil a letter requesting that the company identify, within 60 days of receipt, any valid study that would fulfill this data requirement. Once this 60-day period expires, Virbac will update the Agency as to the information, if any, Virbac receives in response to this "data gap" letter.

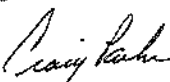
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DATA MATRIX

Date: December 20, 2011			EPA Reg. No./File Symbol 2382-TBA		Page 1 of 9
Applicant's/Registrant's Name & Address Virbac AH, Inc. PO Box 162059 Fort Worth TX 76161			Product: EFFIPRO® PLUS TOPICAL SOLUTION FOR DOGS		
Ingredient: Fipronil, Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Product Chemistry Test Guidelines					
830.1550	Product Identity and Composition	New Submission	Virbac AH, Inc.	OWN	
830.1600	Description of Materials Used	New Submission	Virbac AH, Inc.	OWN	
830.1620	Description of Production Process	New Submission	Virbac AH, Inc.	OWN	
830.1650	Description of Formulation Process	New Submission	Virbac AH, Inc.	OWN	
830.1670	Description of Formation of Impurities	New Submission	Virbac AH, Inc.	OWN	
830.1700	5-Batch Analysis	New Submission	Virbac AH, Inc.	OWN	
830.1750	Certified Limits	New Submission	Virbac AH, Inc.	OWN	
830.1800	Analytical Method	New Submission	Virbac AH, Inc.	OWN	
830.6302	Color	New Submission	Virbac AH, Inc.	OWN	
830.6303	Physical State	New Submission	Virbac AH, Inc.	OWN	
830.6304	Odor	New Submission	Virbac AH, Inc.	OWN	
830.6313	Metal Stability		Virbac AH, Inc.	NR	
830.6314	Oxidation/reduction	New Submission	Virbac AH, Inc.	OWN	
830.6315	Flammability	New Submission	Virbac AH, Inc.	OWN	
830.6316	Explosibility		Virbac AH, Inc.	NR	
830.6317	Storage stability	To be conducted	Virbac AH, Inc.	OWN	
Signature 			Name and Title Craig Parks Vice President, Research & Development		Date December 20, 2011

EPA Form 8570-35 (9-97) Electronic and Paper Versions Available. Submit only Paper version.

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DATA MATRIX

Date December 20, 2011			EPA Reg. No./File Symbol 2382-TBA		Page 2 of 9
Applicant's/Registrant's Name & Address Virbac AH, Inc. PO Box 162059 Fort Worth TX 76161			Product: EFFIPRO® PLUS TOPICAL SOLUTION FOR DOGS		
Ingredient: Fipronil, Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7100	Viscosity	New Submission	Virbac AH, Inc.	OWN	
830.6319	Miscibility		Virbac AH, Inc.	NR	
830.6320	Corrosion characteristics	To be conducted	Virbac AH, Inc.	OWN	
830.6321	Dielectric breakdown voltage		Virbac AH, Inc.	NR	
830.7000	pH	New Submission	Virbac AH, Inc.	OWN	
830.7300	Density, bulk density, or specific gravity	New Submission	Virbac AH, Inc.	OWN	
830.7320	Particle Size distribution		Virbac AH, Inc.	NR	
40 CFR 158.340 Toxicology Data Requirements					
870.1100	Acute oral toxicity	New Submission	Virbac AH, Inc.	OWN	
870.1200	Acute dermal toxicity	New Submission	Virbac AH, Inc.	OWN	
870.1300	Acute inhalation toxicity	Waiver requested	Virbac AH, Inc.		
870.2400	Primary eye irritation	New Submission	Virbac AH, Inc.	OWN	
870.2500	Primary dermal irritation	New Submission	Virbac AH, Inc.	OWN	
870.2600	Dermal sensitization	New Submission	Virbac AH, Inc.	OWN	
Signature 			Name and Title Craig Parks Vice President, Research & Development		Date December 20, 2011

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DATA MATRIX

Date: December 20, 2011

EPA Reg. No./File Symbol 2382-TBA

Page 3 of 9

Applicant's/Registrant's Name & Address

Virbac AH, Inc

PO Box 162059

Fort Worth TX 76161

Product:

EFFIPRO® PLUS TOPICAL SOLUTION FOR DOGS

Ingredient: Fipronil, Pyriproxyfen

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Efficacy and Safety Data					
870.7200	Dog safety	43444905	Merial	OLD	
870.7200	Dog safety	43577711	Merial	OLD	
870.7200	Dog safety	43863802	Merial	OLD	
870.7200	Dog safety	43121110	Merial	OLD	
870.7200	Dog safety	43121111	Merial	OLD	
870.7200	Dog safety	45620507	Merial	PAY	
870.7200	Dog safety	43396408	Ecto Development Corporation	OLD	
870.7200	Dog safety	43612601	Ecto Development Corporation	OLD	
870.7200	Dog safety	44900902	Virbac AH, Inc.	OWN	
870.7200	Dog safety	44900903	Virbac AH, Inc.	OWN	
870.7200	Dog safety	42178309	Sumitomo Chemical Company, Ltd.	OLD	
870.7200	Dog safety	New submission	Virbac AH, Inc.	OWN	
810.3300	Efficacy	43121114	Merial	OLD	
810.3300	Efficacy	43121115	Merial	OLD	
810.3300	Efficacy	43121116	Merial	OLD	
810.3300	Efficacy	43121117	Merial	OLD	
810.3300	Efficacy	43121118	Merial	OLD	
810.3300	Efficacy	43121119	Merial	OLD	
810.3300	Efficacy	43121120	Merial	OLD	

Signature

Name and Title

Craig Parks

Vice President, Research & Development

Date

December

20, 2011

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DATA MATRIX

Date: December 20, 2011			EPA Reg. No./File Symbol 2382-TBA		Page 4 of 9
Applicant's/Registrant's Name & Address Virbac AH, Inc PO Box 162059 Fort Worth TX 76161			Product: EFFIPRO® PLUS TOPICAL SOLUTION FOR DOGS		
Ingredient: Fipronil, Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Efficacy and Safety Data					
810.3300	Efficacy	43121121	Merial	OLD	
810.3300	Efficacy	43121122	Merial	OLD	
810.3300	Efficacy	43444901	Merial	OLD	
810.3300	Efficacy	43577701	Merial	OLD	
810.3300	Efficacy	43577712	Merial	OLD	
810.3300	Efficacy	43577713	Merial	OLD	
810.3300	Efficacy	43951701	Merial	OLD	
810.3300	Efficacy	44088901	Merial	OLD	
810.3300	Efficacy	46006002	Wellmark International	PUBL	
810.3300	Efficacy	44900904	Virbac AH, Inc.	OWN	
810.3300	Efficacy	45020601	Virbac AH, Inc.	OWN	
810.3300	Efficacy	Pending; submitted with Effipro Plus Cat Application		OWN	
810.3300	Efficacy	New submission		OWN	
Signature 			Name and Title Craig Parks Vice President, Research & Development		Date December 20, 2011

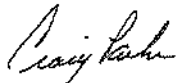
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DATA MATRIX

Date December 20, 2011				EPA Reg. No./File Symbol 2382-TBA		Page 5 of 9
Applicant's/Registrant's Name & Address Virbac AH, Inc PO Box 162059 Fort Worth TX 76161				Product: EFFIPRO® PLUS TOPICAL SOLUTION FOR DOGS		
Ingredient: Fipronil, Pyriproxyfen						
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note	
810.3300	Efficacy	44942011	Merial	PAY		
810.3300	Efficacy	44942106	Merial	PAY		
810.3300	Efficacy	45612701	Merial	PAY		
810.3300	Efficacy	45618501	Merial	PAY		
810.3300	Efficacy	45620501	Merial	PAY		
810.3300	Efficacy	45620502	Merial	PAY		
810.3300	Efficacy	45620503	Merial	PAY		
810.3300	Efficacy	45620504	Merial	PAY		
810.3300	Efficacy	45620505	Merial	PAY		
810.3300	Efficacy	45620506	Merial	PAY		
810.3300	Efficacy	45628101	Merial	PAY		
810.3300	Efficacy	45628102	Merial	PAY		
810.3300	Efficacy	45628103	Merial	PAY		
810.3300	Efficacy	45628104	Merial	PAY		
810.3300	Efficacy	45628105	Merial	PAY		
810.3300	Efficacy	45628201	Merial	PAY		
810.3300	Efficacy	45866901	Merial	PAY		
810.3300	Efficacy	45866902	Merial	PAY		
810.3300	Efficacy	46019201	Merial	PAY		
810.3300	Efficacy	46019202	Merial	PAY		
Signature 			Name and Title Craig Parks Vice President, Research & Development		Date December 20, 2011	

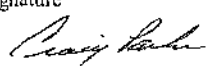
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Date: December 20, 2011		EPA Reg. No./File Symbol 2382-TBA		Page 6 of 9	
Applicant's/Registrant's Name & Address Virbac AH, Inc PO Box 162059 Fort Worth TX 76161		Product: EFFIPRO® PLUS TOPICAL SOLUTION FOR DOGS			
Ingredient: Fipronil, Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Child Resistant Packaging					
40 CFR 157	Evaluation of the 3 ml Applicator Tube with 1.34 ml water, 1 applicator tube test for Child-Resistant Effectiveness	48095221	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 3 ml Applicator Tube with 1.34 ml water, 6 applicators tube test for Child-Resistant Effectiveness	48095222	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 3 ml Applicator Tube with 1.34 ml water, 36 applicators tube test for Child-Resistant Effectiveness	48095223	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 3 ml Applicator Tube with 1.34 ml water, 1 applicator tube test for Senior-Use Effectiveness	48095224	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 3 ml Applicator Tube with 1.34 ml water, 6 applicators tube test for Senior-Use Effectiveness	48095225	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 3 ml Applicator Tube with 1.34 ml water, 36 applicators tube test for Senior-Use Effectiveness	48095226	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 3 ml Applicator Tube with 2.68ml water, 1 applicator tube test for Child-Resistant Effectiveness	48095227	Virbac AH, Inc.	OWN	
Signature 			Name and Title Craig Parks Vice President, Research & Development		Date December 20, 2011

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DATA MATRIX

Date: December 16, 2011		EPA Reg. No./File Symbol 2382-TBA		Page 7 of 9	
Applicant's/Registrant's Name & Address Virbac AH, Inc. PO Box 162059 Fort Worth TX 76161		Product: EFFIPRO® PLUS TOPICAL SOLUTION FOR DOGS			
Ingredient: Fipronil, Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
40 CFR 157	Evaluation of the 3 ml Applicator Tube with 2.68 ml water, 6 applicators tube test for Child-Resistant Effectiveness	48095228	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 3 ml Applicator Tube with 2.68 ml water, 36 applicators tube test for Child-Resistant Effectiveness	48095229	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 3 ml Applicator Tube with 2.68 ml water, 1 applicator tube test for Senior-Use Effectiveness	48095230	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 3 ml Applicator Tube with 2.68 ml water, 6 applicators tube test for Senior-Use Effectiveness	48095231	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 3 ml Applicator Tube with 2.68 ml water, 36 applicators tube test for Senior-Use Effectiveness	48095232	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 6 ml Applicator Tube with 4.02 ml water, 1 applicator tube test for Child-Resistant Effectiveness	48095233	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 6 ml Applicator Tube with 4.02 ml water, 6 applicators tube test for Child-Resistant Effectiveness	48095234	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 6 ml Applicator Tube with 4.02 ml water, 36 applicators tube test for Child-Resistant Effectiveness	48095235	Virbac AH, Inc.	OWN	
Signature 			Name and Title Craig Parks Vice President, Research & Development		Date December 20, 2011

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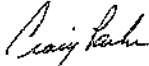
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Applicant's/Registrant's Name & Address Virbac AH, Inc. PO Box 162059 Fort Worth TX 76161			Product: EFFIPRO® PLUS TOPICAL SOLUTION FOR DOGS		
Ingredient: Fipronil, Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
40 CFR 157	Evaluation of the 1ml applicator tube with 0.67 ml water, 1 applicator tube test for Child-Resistant Effectiveness	48410001	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 1ml applicator tube with 0.67 ml water, 1 applicator tube test for Senior-Use Effectiveness	48410002	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 1ml applicator tube with 0.67 ml water, 6 applicator tube test for Child-Resistant Effectiveness	48410003	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 1ml applicator tube with 0.67 ml water, 6 applicator tube test for Senior-Use Effectiveness	48410004	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 1ml applicator tube with 0.67 ml water, 36 applicator tube test for Child-Resistant Effectiveness	48410005	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 1ml applicator tube with 0.67 ml water, 36 applicator tube test for Senior-Use Effectiveness	48410006	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 1ml applicator tube with 0.67 ml water, 3 applicator tube test for Child-Resistant Effectiveness	48410007	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 1ml applicator tube with 0.67 ml water, 3 applicator tube test for Senior-Use Effectiveness	48410008	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 3ml applicator tube with 1.34 ml water, 3 applicator tube test for Child-Resistant Effectiveness	48410009	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 3ml applicator tube with 1.34 ml water, 3 applicator tube test for Senior-Use Effectiveness	48410010	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 3ml applicator tube with 2.68 ml water, 3 applicator tube test for Child-Resistant Effectiveness	48410011	Virbac AH, Inc.	OWN	
Signature 			Name and Title Craig Parks Vice President, Research & Development		Date December 20, 2011

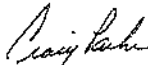
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Applicant's/Registrant's Name & Address Virbac AH, Inc PO Box 162059 Fort Worth TX 76161		Product: EFFIPRO® PLUS TOPICAL SOLUTION FOR DOGS			
Ingredient: Fipronil, Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
40 CFR 157	Evaluation of the 3ml applicator tube with 2.68 ml water, 3 applicator tube test for Senior-Use Effectiveness	48410012	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 1ml applicator tube with 4.02 ml water, 3 applicator tube test for Child-Resistant Effectiveness	48410013	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 1ml applicator tube with 4.02 ml water, 3 applicator tube test for Senior-Use Effectiveness	48410014	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 3ml applicator tube with 2.68 ml water, 1 applicator tube test for Senior-Use Effectiveness	48410015	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 3ml applicator tube with 2.68 ml water, 36 applicator tube test for Senior-Use Effectiveness	48410016	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 6ml applicator tube with 4.02 ml water, 6 applicator tube test for Senior-Use Effectiveness	48410017	Virbac AH, Inc.	OWN	
Signature 			Name and Title Craig Parks Vice President, Research & Development		Date December 20, 2011

Decision Information for 2382-RIO

Decision Seq: 459013	Action Code: R310, NEW PRODUCT, NON-FAST TRACK (INCLUDES REVIEWS O ...)			Decision Status
FFS Start Date: 10-Jan-2012	Tentative Ind: No	FFS Original Decision: ...	Tracking	
Due Date: 10-Jul-2012	75-Day Due Date: ...	FFS EUP Decision: ...	Create Resubmission	
OPP Target Due Dt: ...	21-Day Screen Dt: 10-Jan-2012	FFS Primary Decision: ...	FFS Letters	
Negotiated Due Dt: ...	Start/Stop Clock: FQPA Clock: ...		75 Day Letters	
Registrant: ...	Days Elapsed: ...		Action Code History	
Response Due Date: ...			Secondary Decision	
Current Status: PENDING (22-Dec-2011)				
Decision Comments	Payment	Unmatched Payments	75 Day Letters	
Meetings & Milestones	FFS Information	FFS Negotiated Due Dates	OPP Target Due Date	
Decision Ownership	Receipts	Data Package	Reduced Risk	

Receipts	Staff Member	Reg/DCI Number	Submission Due Dt	Response
S: 811475	Akinlosotu, Bonaventure	2382-RIO	10-Jul-2012	PENDING
Submission of addition of citations to the Data Matrix				
S: 808748	Akinlosotu, Bonaventure	2382-RIO	10-Jul-2012	PENDING
New Registration				

Viewing Record 1 of 1

Received 2/15/2015 Resubmission

BA

Decision Information for 2382-RIO

Decision Seq: 459013	Action Code: R310, NEW PRODUCT; NON-FAST TRACK (INCLUDES REVIEWS)		Decision Status
FFS Start Date: 10-Jan-2012	Tentative Ind: No	FFS Original Decision:	Tracking
Due Date: 10-Jul-2012	75-Day Due Date:	FFS EUP Decision:	Create Resubmission
OPP Target Due Dt:	21-Day Screen Dt: 10-Jan-2012	FFS Primary Decision:	FFS Letters
Negotiated Due Dt:	Start/Stop Clock: FQPA Clock:		Waiver Documentation
Registrant:	Days Elapsed:		Action Code History
Response Due Date:	Current Status: PENDING (22-Dec-2011)		Secondary Decision

- | | | | |
|-----------------------|-----------------|--------------------------|---------------------|
| Decision Comments | Payment | Unmatched Payments | 75 Day Letters |
| Meetings & Milestones | FFS Information | FFS Negotiated Due Dates | OPP Target Due Date |
| Decision Ownership | Receipts | Data Package | Reduced Risk |

Receipts	Staff Member	Reg/DCI Number	Submission Due Dt	Response
S:908748	Akinlosotu, Bonaventure	2382-RIO	10-Jul-2012	PENDING
New Registration				

Viewing Record 1 of 1

Received 1/31/2012 BA

Fee for Service

{908748U~

This package includes the following

- ☒ New Registration
- ☐ Amendment

- ☒ Studies? ☐ Fee Waiver?
- ☐ volpay % Reduction: _____

for Division

- ☐ AD
- ☐ BPPD
- ☒ RD

Risk Mgr. **10**

Receipt No.

S-

908748

EPA File Symbol/Reg. No.

2382-RIO

Pin-Punch Date:

12/20/2011

- ☐ This item is NOT subject to FFS action.

Action Code:

Requested:

2310
2340

Granted:

2310

Amount Due: \$ **4807.00**

Parent/Child Decisions:

☒ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: **W. L. S.**

Date: **12/21/11**

Remarks:

PRIA 2 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

3/23/09

21 Day Screen Start Date: 12-20-11

Experts In-Processing Signature: MF Harrington Date 12-22-11 Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐ Date _____

EPA Reg. Number: <u>2382-R10</u>		EPA Receipt Date: <u>12-20-11</u>				
Items for Review				Yes	No	N/A*
1	Application Form (EPA Form 8570-1)(link to form) signed & complete including package type			X		
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4) (Link to form)			X		
	a) All inerts (link to http://www.epa.gov/oppr001/inerts/), including fragrances, approved for the proposed uses (see Footnote A)	yes	no			
	X					
3	Certification with Respect to Citation of Data (EPA Form 8570-34) (Link to form) completed and signed (N/A if 100% repack)			X		
	Certificate and data matrix consistent			X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes	no			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	Formulator's Exemption Statement (EPA Form 8570-27) (Link to form) completed and signed (N/A if source is unregistered or applicant owns the technical)			X		
5	Data Matrix (EPA Form 8570-35) (Link to form) both internal and external copies (PR 98-5) (Link to PR 98-5) completed and signed (N/A if 100% repack)			X		
	a) Selective Method (Fee category experts use)	yes	no			
		X				
	b) Cite-All (Fee category experts use)					
	c) Applicant owns all data (Fee category experts use)					
6	5 Copies of Label (link to http://www.epa.gov/oppfead1/labeling/lrm/) (Electronic labels on CD are encouraged and guidance is available)(link to http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm#labels)			X		

7	Is the data package consistent with PR Notice 86-5 (link to PRN 86-5)	X		
8	Notice of Filing (link to http://www.epa.gov/pesticides/regulating/tolerance_petitions.htm) included with petitions (link to http://www.epa.gov/pesticides/regulating/tolerances.htm)			X
9	If applicable for conventional applications, reduced risk rationale (link to http://www.epa.gov/opprd001/workplan/reducedrisk.html)			X
10	Required Data (link to http://www.epa.gov/pesticides/regulating/data_requirements.htm) and/or data waivers. See Footnote C.			
	a) List study (or studies) not included with application			

Comments:

* Inerts approved for non food use

Socket Pass
86-5 Pass

PG/AB

NRID 486969

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses. If an unapproved inert is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses **even if a product is currently registered** by consulting the inert Web

site [link to <http://www.epa.gov/opprd001/inerts/lists.html>] and if the inert is not approved, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient**. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch [Link to http://www.epa.gov/oppbppd1/biopesticides/contacts_bppd.htm].

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information [link to <http://www.epa.gov/opprd001/inerts/tips.pdf>] must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R311, R312 or R313), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.

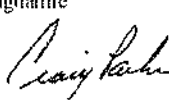
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DATA MATRIX

Date: February 6, 2012			EPA Reg. No./File Symbol: 2382-R10	Page 1 of 9
Applicant's/Registrant's Name & Address Virbac AH, Inc. PO Box 162059 Fon Worth, TX 76161			Product: EFFIPRO® PLUS TOPICAL SOLUTION FOR DOGS	
Ingredient: Fipronil, Pyriproxyfen				
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status Note
Product Chemistry Test Guidelines				
830.1550	Product Identity and Composition	New Submission	Virbac AH, Inc.	OWN
830.1600	Description of Materials Used	New Submission	Virbac AH, Inc.	OWN
830.1620	Description of Production Process	New Submission	Virbac AH, Inc.	OWN
830.1650	Description of Formulation Process	New Submission	Virbac AH, Inc.	OWN
830.1670	Description of Formulation of Impurities	New Submission	Virbac AH, Inc.	OWN
830.1700	5-Batch Analysis	New Submission	Virbac AH, Inc.	OWN
830.1750	Certified Limits	New Submission	Virbac AH, Inc.	OWN
830.1800	Analytical Method	New Submission	Virbac AH, Inc.	OWN
830.6302	Color	New Submission	Virbac AH, Inc.	OWN
830.6303	Physical State	New Submission	Virbac AH, Inc.	OWN
830.6304	Odor	New Submission	Virbac AH, Inc.	OWN
830.6313	Metal Stability		Virbac AH, Inc.	NR
830.6314	Oxidation/reduction	New Submission	Virbac AH, Inc.	OWN
830.6315	Flammability	New Submission	Virbac AH, Inc.	OWN
830.6316	Explosibility		Virbac AH, Inc.	NR
830.6317	Storage stability	To be conducted	Virbac AH, Inc.	OWN
Signature 			Name and Title Craig Parks Vice President, Research & Development	Date February 6, 2012

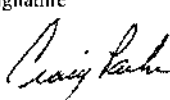
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DATA MATRIX

Date February 6, 2012			EPA Reg. No./File Symbol 2382-RIO		Page 2 of 9
Applicant's/Registrant's Name & Address Virbac AH, Inc PO Box 162059 Fort Worth TX 76161			Product: EFFIPRO® PLUS TOPICAL SOLUTION FOR DOGS		
Ingredient: Fipronil, Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7100	Viscosity	New Submission	Virbac AH, Inc.	OWN	
830.6319	Miscibility		Virbac AH, Inc.	NR	
830.6320	Corrosion characteristics	To be conducted	Virbac AH, Inc.	OWN	
830.6321	Dielectric breakdown voltage		Virbac AH, Inc.	NR	
830.7000	pH	New Submission	Virbac AH, Inc.	OWN	
830.7300	Density, bulk density, or specific gravity	New Submission	Virbac AH, Inc.	OWN	
830.7320	Particle Size distribution		Virbac AH, Inc.	NR	
40 CFR 158.340 Toxicology Data Requirements					
870.1100	Acute oral toxicity	New Submission	Virbac AH, Inc.	OWN	
870.1200	Acute dermal toxicity	New Submission	Virbac AH, Inc.	OWN	
870.1300	Acute inhalation toxicity	Waiver requested	Virbac AH, Inc.		
870.2400	Primary eye irritation	New Submission	Virbac AH, Inc.	OWN	
870.2500	Primary dermal irritation	New Submission	Virbac AH, Inc.	OWN	
870.2600	Dermal sensitization	New Submission	Virbac AH, Inc.	OWN	
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Applicant's/Registrant's Name & Address Virbac AH, Inc PO Box 162059 Fort Worth TX 76161			Product: EFFIPRO® PLUS TOPICAL SOLUTION FOR DOGS		
Ingredient: Fipronil, Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Efficacy and Safety Data					
870.7200	Dog safety	43444905	Merial	OLD	
870.7200	Dog safety	43577711	Merial	OLD	
870.7200	Dog safety	43863802	Merial	OLD	
870.7200	Dog safety	43121110	Merial	OLD	
870.7200	Dog safety	43121111	Merial	OLD	
870.7200	Dog safety	45620507	Merial	PAY	
870.7200	Dog safety	43396408	Ecto Development Corporation	OLD	
870.7200	Dog safety	43612601	Ecto Development Corporation	OLD	
870.7200	Dog safety	44900902	Virbac AH, Inc.	OWN	
870.7200	Dog safety	44900903	Virbac AH, Inc.	OWN	
870.7200	Dog safety	42178309	Sumitomo Chemical Company, Ltd.	OLD	
870.7200	Dog safety	New submission	Virbac AH, Inc.	OWN	
810.3300	Efficacy	43121114	Merial	OLD	
810.3300	Efficacy	43121115	Merial	OLD	
810.3300	Efficacy	43121116	Merial	OLD	
810.3300	Efficacy	43121117	Merial	OLD	
810.3300	Efficacy	43121118	Merial	OLD	
810.3300	Efficacy	43121119	Merial	OLD	
810.3300	Efficacy	43121120	Merial	OLD	
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Date: February 6, 2012			EPA Reg. No./File Symbol: 2382-R10		Page 4 of 9
Applicant's/Registrant's Name & Address Virbac AH, Inc PO Box 162059 Fort Worth TX 76161			Product: EFFIPRO® PLUS TOPICAL SOLUTION FOR DOGS		
Ingredient: Fipronil, Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Efficacy and Safety Data					
810.3300	Efficacy	43121121	Merial	OLD	
810.3300	Efficacy	43121122	Merial	OLD	
810.3300	Efficacy	43444901	Merial	OLD	
810.3300	Efficacy	43577701	Merial	OLD	
810.3300	Efficacy	43577712	Merial	OLD	
810.3300	Efficacy	43577713	Merial	OLD	
810.3300	Efficacy	43951701	Merial	OLD	
810.3300	Efficacy	44088901	Merial	OLD	
810.3300	Efficacy	46006002	Wellmark International	PUBL	
810.3300	Efficacy	44900904	Virbac AH, Inc.	OWN	
810.3300	Efficacy	45020601	Virbac AH, Inc.	OWN	
810.3300	Efficacy	Pending; submitted with Effipro Plus Cat Application		OWN	
810.3300	Efficacy	New submission		OWN	
Signature 			Name and Title Craig Parks Vice President, Research & Development		Date February 6, 2012

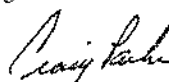
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Applicant's/Registrant's Name & Address Virbac AH, Inc PO Box 162059 Fort Worth TX 76161				Product: EFFIPRO® PLUS TOPICAL SOLUTION FOR DOGS		
Ingredient: Fipronil, Pyriproxyfen						
Guideline Reference Number	Guideline Study Name	MRIID Number	Submitter	Status	Note	
810.3300	Efficacy	44942011	Merial	PAY		
810.3300	Efficacy	44942106	Merial	PAY		
810.3300	Efficacy	45612701	Merial	PAY		
810.3300	Efficacy	45618501	Merial	PAY		
810.3300	Efficacy	45620501	Merial	PAY		
810.3300	Efficacy	45620502	Merial	PAY		
810.3300	Efficacy	45620503	Merial	PAY		
810.3300	Efficacy	45620504	Merial	PAY		
810.3300	Efficacy	45620505	Merial	PAY		
810.3300	Efficacy	45620506	Merial	PAY		
810.3300	Efficacy	45628101	Merial	PAY		
810.3300	Efficacy	45628102	Merial	PAY		
810.3300	Efficacy	45628103	Merial	PAY		
810.3300	Efficacy	45628104	Merial	PAY		
810.3300	Efficacy	45628105	Merial	PAY		
810.3300	Efficacy	45628201	Merial	PAY		
810.3300	Efficacy	45866901	Merial	PAY		
810.3300	Efficacy	45866902	Merial	PAY		
810.3300	Efficacy	46019201	Merial	PAY		
810.3300	Efficacy	46019202	Merial	PAY		
Signature 			Name and Title Craig Parks Vice President, Research & Development		Date February 6, 2012	

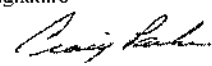
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Date: February 6, 2012			EPA Reg. No./File Symbol: 2382-R10		Page 6 of 9
Applicant's/Registrant's Name & Address Virbac AH, Inc PO Box 162059 Fort Worth TX 76161			Product: EFFIPRO® PLUS TOPICAL SOLUTION FOR DOGS		
Ingredient: Fipronil, Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Child Resistant Packaging					
40 CFR 157	Evaluation of the 3 ml Applicator Tube with 1.34 ml water, 1 applicator tube test for Child-Resistant Effectiveness	48095221	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 3 ml Applicator Tube with 1.34 ml water, 6 applicators tube test for Child-Resistant Effectiveness	48095222	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 3 ml Applicator Tube with 1.34 ml water, 36 applicators tube test for Child-Resistant Effectiveness	48095223	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 3 ml Applicator Tube with 1.34 ml water, 1 applicator tube test for Senior-Use Effectiveness	48095224	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 3 ml Applicator Tube with 1.34 ml water, 6 applicators tube test for Senior-Use Effectiveness	48095225	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 3 ml Applicator Tube with 1.34 ml water, 36 applicators tube test for Senior-Use Effectiveness	48095226	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 3 ml Applicator Tube with 2.68ml water, 1 applicator tube test for Child-Resistant Effectiveness	48095227	Virbac AH, Inc.	OWN	
Signature 			Name and Title Craig Parks Vice President, Research & Development		Date February 6, 2012

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Applicant's/Registrant's Name & Address Virbac AH, Inc PO Box 162059 Fort Worth TX 76161				Product: EFFIPRO® PLUS TOPICAL SOLUTION FOR DOGS		
Ingredient: Fipronil, Pyriproxyfen						
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note	
40 CFR 157	Evaluation of the 3 ml Applicator Tube with 2.68 ml water, 6 applicators tube test for Child-Resistant Effectiveness	48095228	Virbac AH, Inc.	OWN		
40 CFR 157	Evaluation of the 3 ml Applicator Tube with 2.68 ml water, 36 applicators tube test for Child-Resistant Effectiveness	48095229	Virbac AH, Inc.	OWN		
40 CFR 157	Evaluation of the 3 ml Applicator Tube with 2.68 ml water, 1 applicator tube test for Senior-Use Effectiveness	48095230	Virbac AH, Inc.	OWN		
40 CFR 157	Evaluation of the 3 ml Applicator Tube with 2.68 ml water, 6 applicators tube test for Senior-Use Effectiveness	48095231	Virbac AH, Inc.	OWN		
40 CFR 157	Evaluation of the 3 ml Applicator Tube with 2.68 ml water, 36 applicators tube test for Senior-Use Effectiveness	48095232	Virbac AH, Inc.	OWN		
40 CFR 157	Evaluation of the 6 ml Applicator Tube with 4.02 ml water, 1 applicator tube test for Child-Resistant Effectiveness	48095233	Virbac AH, Inc.	OWN		
40 CFR 157	Evaluation of the 6 ml Applicator Tube with 4.02 ml water, 6 applicators tube test for Child-Resistant Effectiveness	48095234	Virbac AH, Inc.	OWN		
40 CFR 157	Evaluation of the 6 ml Applicator Tube with 4.02 ml water, 36 applicators tube test for Child-Resistant Effectiveness	48095235	Virbac AH, Inc.	OWN		
Signature 			Name and Title Craig Parks Vice President, Research & Development		Date February 6, 2012	

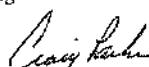
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Applicant's/Registrant's Name & Address Virbac AH, Inc PO Box 162059 Fort Worth TX 76161				Product: EFFIPRO® PLUS TOPICAL SOLUTION FOR DOGS	
Ingredient: Fipronil, Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
40 CFR 157	Evaluation of the 1ml applicator tube with 0.67 ml water, 1 applicator tube test for Child-Resistant Effectiveness	48410001	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 1ml applicator tube with 0.67 ml water, 1 applicator tube test for Senior-Use Effectiveness	48410002	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 1ml applicator tube with 0.67 ml water, 6 applicator tube test for Child-Resistant Effectiveness	48410003	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 1ml applicator tube with 0.67 ml water, 6 applicator tube test for Senior-Use Effectiveness	48410004	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 1ml applicator tube with 0.67 ml water, 36 applicator tube test for Child-Resistant Effectiveness	48410005	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 1ml applicator tube with 0.67 ml water, 36 applicator tube test for Senior-Use Effectiveness	48410006	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 1ml applicator tube with 0.67 ml water, 3 applicator tube test for Child-Resistant Effectiveness	48410007	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 1ml applicator tube with 0.67 ml water, 3 applicator tube test for Senior-Use Effectiveness	48410008	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 3ml applicator tube with 1.34 ml water, 3 applicator tube test for Child-Resistant Effectiveness	48410009	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 3ml applicator tube with 1.34 ml water, 3 applicator tube test for Senior-Use Effectiveness	48410010	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 3ml applicator tube with 2.68 ml water, 3 applicator tube test for Child-Resistant Effectiveness	48410011	Virbac AH, Inc.	OWN	
Signature 			Name and Title Craig Parks Vice President, Research & Development		Date February 6, 2012

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Applicant's/Registrant's Name & Address Virbac AH, Inc PO Box 162059 Fort Worth TX 76161		Product: EFFIPRO® PLUS TOPICAL SOLUTION FOR DOGS			
Ingredient: Fipronil, Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
40 CFR 157	Evaluation of the 3ml applicator tube with 2.68 ml water, 3 applicator tube test for Senior-Use Effectiveness	48410012	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 1ml applicator tube with 4.02 ml water, 3 applicator tube test for Child-Resistant Effectiveness	48410013	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 1ml applicator tube with 4.02 ml water, 3 applicator tube test for Senior-Use Effectiveness	48410014	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 3ml applicator tube with 2.68 ml water, 1 applicator tube test for Senior-Use Effectiveness	48410015	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 3ml applicator tube with 2.68 ml water, 36 applicator tube test for Senior-Use Effectiveness	48410016	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 6ml applicator tube with 4.02 ml water, 6 applicator tube test for Senior-Use Effectiveness	48410017	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 6ml applicator tube with 4.02 ml water, 1 applicator tube test for Senior-Use Effectiveness	48095236	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 6ml applicator tube with 4.02 ml water, 36 applicator tube test for Senior-Use Effectiveness	48095238	Virbac AH, Inc.	OWN	
Signature 			Name and Title Craig Parks Vice President, Research & Development		Date February 6, 2012



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

December 27, 2011

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

VIRBAC AH, INC.
VIRBAC AH, INC.
13001 ST. CHARLES ROCK ROAD
BRIDGETON, MO 63044

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 20-DEC-11. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

December 22, 2011

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OPP Decision Number: D-459013
EPA File Symbol or Registration Number: 2382-RIO
Product Name: EFFIPRO PLUS TOPICAL SOLUTION FOR DOGS
EPA Receipt Date: 20-Dec-2011
EPA Company Number: 2382
Company Name: VIRBAC AH, INC.

CRAIG PARKS, MS, DVM
VIRBAC AH, INC.
P.O. BOX 162059
FORT WORTH, TX 76161

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R310

NEW PRODUCT;NON-FAST TRACK (INCLUDES REVIEWS OF PRODUCT
CHEMISTRY;ACUTE TOXICITY;PUBLIC HEALTH PEST EFFICACY);

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee
Ombudsman at (703) 308-9362.

Sincerely,

A handwritten signature in black ink, appearing to read "M. J. Lee", is written over the typed name.

Front End Processing Staff

Information Technology & Resources Management Division



48696900

December 20, 2011

Richard Gebken, PM 10
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Document Processing Desk (REGFEE)
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Subject: EFFIPRO® PLUS Topical Solution for Dogs (EPA File Symbol 2382-TBA);
New Product Application.

Dear Mr. Gebken,

Virbac Animal Health (Virbac AH, Inc. P. O. Box 162059, Ft. Worth, TX 76137, (Company Number 2382)) is hereby submitting an application to register the spot-on pesticide product EFFIPRO® PLUS Topical Solution for Dogs.

This product contains the active ingredients fipronil and pyriproxyfen and is intended to control fleas, ticks, mosquitoes, and other pests on dogs only.

Pyriproxyfen itself is registered alone and in combination with other active ingredients in numerous end use products for spot-on insect growth regulator use on dogs.

As indicated on Form 8570-34, Virbac is using the selective method to address applicable data requirements for this application pursuant to 40 CFR 152.90. Pursuant to 40 CFR 152.93, Offer to Pay letters are being sent to the submitters of data cited in Virbac's application that were originally submitted within the past 15 years.

Below is a list of the components included with this application:

1. Cover Letter;
2. Transmittal Document;
3. Application for Pesticide Form 8570-1;
4. Confidential Statement of Formula-2 Copies;
5. Data Matrix Form 8570-4; (EUP and TGA1);
6. Certification of Data Citation Form 8570-34;
7. Proposed Label - 5 copies;
8. 3 copies of bound PR 86-5 compliant study reports supporting registration;
9. Waiver Request for Acute Inhalation Study (attached to Cover Letter);
10. Letter of Self-certification of Child-Resistant Packaging;
11. Formulator's Exemption Form 8570-27; and
12. Copy of PRIA Check for category R-310 (\$4807).

Child-Resistant Packaging

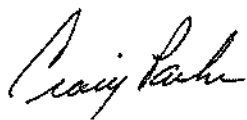
EFFIPRO® PLUS Topical Solution for Dogs and will be marketed in single dose unit applicators in packages of 1, 3, 6, and 36. These single dose applicators for the 0.67 ml, 1.34 ml, 2.68 ml, and 4.02 ml dose sizes have been previously tested, and CRP certification has been accepted by EPA. All relevant test data supporting self-certification have been reviewed and are cited in the attached Data Matrix. A self-certification letter is also attached.

PRIA Considerations

After reviewing the Agency's PRIA category interpretations, we believe that the R-310 PRIA category and a 6 month review period is appropriate for this product. Consequently, please find a copy of one previously submitted check in the amount of \$4807 to cover the PRIA fee.

Should you have any questions about this application package, please do not hesitate to contact me via telephone at 682-647-3576 or via e-mail at craig.parks@virbacus.com.

Sincerely,



Craig Parks, MS, DVM
Vice President, Research & Development
Virbac Animal Health, Inc.

Attachments

TRANSMITTAL DOCUMENT

NAME AND ADDRESS OF SUBMITTER:

Virbac, Inc. (EPA Company Number 2382)
P.O. Box 162059
Fort Worth, TX 76161

REGULATORY ACTION SUPPORTED BY THIS PACKAGE:


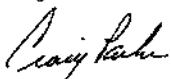
This submission is an application to register an end use pro namely EFFIPRO[®] PLUS Topical Solution for Dogs. Effipro[®] EFFIPRO[®] PLUS Topical Solution for Dogs contains the active ingredients Fipronil and Pyriproxyfen.

SUBMITTAL DATE:

December 20, 2011

Volume	Study Title	MRID No.
1	Administrative Materials Effipro [®] Plus Topical Solution for Dogs	
	<i>Group A Product Chemistry</i>	
2	OPPTS 830.1550, 830.1750, 830.1600, 830.1620, 830.1650, 830.1670 EFFIPRO [®] PLUS Topical Solution for Dogs	48696901
	<i>Group B Product Chemistry</i>	
3	OPPTS 830.6302, 830.6303, 830.6304 Determination of the Physico-Chemical Property "Appearance (Color, Physical State and Odor)"	48696902
4	OPPTS 830.6314 Determination of Oxidation / Reduction (Chemical Incompatibility)	48696903
5	OPPTS 830.6315 Determination of the Physico-Chemical Property "Flash Point"	48696904
6	OPPTS 830.7000 Determination of the Physico-Chemical Property "pH"	48696905
7	OPPTS 830.7100 Determination of Physico-Chemical Property "Viscosity"	48696906
8	OPPTS 830.7300 Determination of the Physico-Chemical Property "Relative Density"	48696907

Volume	Study Title	MRID No.
9	OPPTS 830.1700, 830.1800 Quantification of the Active Ingredients Fipronil and Pyriproxyfen in Five Batches by Validated Methods	48696908
10	OPPTS 830.1800 Enforcement Analytical Method – Quantification of the Active Ingredients Fipronil and Pyriproxyfen	48696909
	<i>Acute Toxicity</i>	
11	OPPTS 870.1100 Acute Oral Toxicity Study in Rats – Up-and-Down-Procedure	48696910
12	OPPTS 870.1200 Acute Dermal Toxicity Study in Rats	48696911
13	OPPTS 870.2400 Acute Eye Irritation Study in Rabbits	48696912
14	OPPTS 870.2500 Acute Dermal Irritation Study in Rabbits	48696913
15	OPPTS 870.2600 Contact Hypersensitivity in Albino Guinea Pigs, Buehler Test	48696914
	<i>Product Performance</i>	
16	OPPTS 810.3300 Summary of Efficacy Data for EFFIPRO® PLUS Topical Solution for Dogs	48696915
	<i>Product Safety</i>	
17	OPPTS 870.7200 Summary of Companion Animal Safety Data for EFFIPRO® PLUS Topical Solution for Dogs	48696916

 <div style="display: inline-block; vertical-align: middle; text-align: center;"> United States Environmental Protection Agency Washington, DC 20460 </div>		<input checked="" type="checkbox"/> Registration <input type="checkbox"/> Amendment <input type="checkbox"/> Other	OPP Identifier Number
Application for Pesticide – Section I			
1. Company/Product Number Virbac AH, Inc./ 2382- TBA		2. EPA Product Manager Richard Gebken	
4. Company/Product (Name) EFFIPRO PLUS Topical Solution for Dogs		3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted	
5. Name and Address of Applicant (Include ZIP Code) Virbac AH, Inc P.O. Box 162059 Fort Worth, TX 76161 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg No. _____ Product Name _____	
Section - II			
<input type="checkbox"/> Amendment – Explain below <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input type="checkbox"/> Notification – Explain below		<input type="checkbox"/> Final printed labels in response to Agency letter dated _____ <input type="checkbox"/> "Me Too" Application <input checked="" type="checkbox"/> Other – Explain below	
Explanation: Use additional page(s) if necessary. (For Section I and Section II.)			
Application for registration. PRIA Category R310. Please refer to attached letter			
Section III			
1. Material This Product Will be Packaged in:			
Child-Resistant Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" Unit Packaging wgt. 0.67ml, 1.34 ml, 2.68 ml, 4.02 ml	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Package wgt No. per container 1,3,6,36	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic, PETE <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
3. Location of Net Contents Information <input type="checkbox"/> Label <input checked="" type="checkbox"/> Container		4. Size(s) Retail Container 1, 3, 6, 36 ml tubes	
5. Location of label directions <input checked="" type="checkbox"/> On Label <input checked="" type="checkbox"/> On Label accompanying product		6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled <input type="checkbox"/> Other _____	
Section IV			
1. Contact Person (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Craig Parks, MS, DVM		Title Vice President of Research and Development, Virbac AH, Inc. Telephone No. (Include Area Code) 682-647-3576	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)
2. Signature 		3. Title Vice President of Research and Development, Virbac AH, Inc.	
4. Typed Name Craig Parks, MS, DVM		5. Date 12-19-11	



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, Collection Strategies Division (2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number
 Virbac AH, Inc./ PO Box 162059 Fort Worth TX/ 682-647-3576

EPA Registration Number/File Symbol
 2382-TBA

Active Ingredient(s) and/or representative test compound(s)
 Fipronil, pyriproxyfen

Date
 12/19/11

General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158)
 indoor residential

Product Name
 EFFIPRO PLUS Topical Solution for Dogs

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature

Craig Parks

Date

12/19/11

Typed or Printed Name and Title

Craig Parks, VP of Research and Development



United States
Environmental Protection Agency
Washington, DC 20460

Formulator's Exemption Statement
(40 CFR 152.85)

Applicant's Name and Address

Virbac Animal Health
P. O. Box 162059
Ft. Worth, TX 76137

EPA File Symbol/Registration Number

2382-TBA

Product Name

EFFIPRO PLUS TOPICAL SOLUTION FOR DOGS

Date of Confidential Statement of Formula (EPA Form 8570-4)

October 21, 2011

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s): pyriproxifen

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another producer, and is labeled for at least each use for which my product is proposed to be labeled.

(3) Indicate by checking (A) or (B) below which paragraph applies:


☒ (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1)

OR

☐ (B) The Confidential Statement of Formula (CSF) (EPA Form 8750-4) referenced above and on file with the EPA is complete, current, and accurate and contains the information required on the current CSF

(4) The following active ingredients in this product qualify for the formulator's exemption

Source

Active Ingredient	Product Name	Registration Number
Pyriproxifen	[REDACTED]	[REDACTED]
Signature 	Name and Title Vice President, Research & Development	Date December 19, 2011



December 19, 2011

Richard Gebken, PM 10
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Document Processing Desk
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Subject: Child Resistant Packaging Certification
EFFIPRO® PLUS Topical Solution for Dogs;
EPA Reg. No. 2382-NEW

Dear Mr. Gebken:

I certify that the packaging used for the following product meets the standards of 40 CFR 157.32, including the revised standards in 16 CFR 1700.15(b), when tested by the revised testing procedures in 16 CFR 1700.20, as published in 60 FR 37710 (July 21, 1995).

- EFFIPRO® PLUS Topical Solution for Dogs (EPA Reg. No. 2382-NEW).

Virbac Animal Health (Virbac AH, Inc. P. O. Box 162059, Ft. Worth, TX, 76137; (Company Number 2382) is submitting this child resistant packaging certification to support the pending new product application filed on the above date for EFFIPRO® PLUS Topical Solution for Dogs (EPA Reg. No. 2382-NEW).

Should you have any questions about this letter, please do not hesitate to contact me via telephone at 682-647-3576 or via e-mail at craig.parks@virbacus.com.

Sincerely,

A handwritten signature in black ink, appearing to read "Craig Parks". The signature is fluid and cursive.

Craig Parks, MS, DVM
Vice President, Research & Development
Virbac Animal Health, Inc.

Registrant: Virbac Animal Health, Inc.
Acute Inhalation Study (OPPTS 830.1300).
Effipro Plus Topical Solution for Dogs.

The potential human inhalation exposure to this product is expected to be negligible. Only very small amounts of product are applied per application, depending on the weight of the animal. Based on packaging considerations described in the proposed product labeling, the maximum volume of Effipro® Plus Topical Solution for Dogs that can be administered at one time to a dog using the largest available applicator size is approximately 4.0 ml. This application volume represents the worst case because it is the dose that is recommended only for use on dogs weighing more than 89 pounds. Therefore, according to the proposed label, a great deal of anticipated product use will occur at much lower volumes on smaller dogs.

Furthermore, the measured vapor pressure of both of the active ingredients, fipronil and pyriproxifen, are extremely low (2.8×10^{-9} mm Hg at 25°C and 1.0×10^{-7} mm Hg at 25°C , respectively), indicating that both active ingredients are essentially non-volatile and are therefore not expected to vaporize from the skin of the treated animal following application. The active ingredients will therefore not be available for inhalation after application according to label directions. Finally, the method of applying the liquid product directly to the pet creates no particulates, aerosols, or other respirable matter. Therefore, based on the criteria provided by the Agency in 40 CFR 158.500, footnote 4 under the Toxicology Data Requirements, a waiver of the acute inhalation study for these products is appropriate.

[illegible]

End Use (EP) or Manufacturing Use (MP) product or Technical Grade of the Active Ingredient (TGA).
 Must submit Group A and B product chemistry data for each proposed product unless it's a 100% identical (repack): YES or NO (circle one)

Guideline No.	Group A: Product Chemistry Data Study Title	EP Data Submitted		MP Data Submitted		TGA	
		Yes	No	Yes	No	Yes	No
830.1550	Product Identity & Composition	X					
830.1600	Description of materials used to produce the product	X					
830.1650	Description of formulation process	X					
830.1670	Discussion on the formation of impurities	X					
830.1700	Preliminary analysis	X					
830.1750	Certified limits (158.345)	X					
830.1800	Enforcement analytical method	X					

Guideline No.	Group B: Product Chemistry Data Study Title	EP Data Submitted		MP Data Submitted		TGA	
		Yes	No	Yes	No	Yes	No
830.6302	Color	X					
830.6303	Physical State	X					
830.6304	Odor	X					
830.6313	Stability to normal and elevated temperatures metal and metal ions						
830.6314	Oxidation/Reduction (Chemical incompatibility)	X					
830.6315	Flammability	X					
830.6316	Explosibility	X					
830.6317	Storage stability	X					
830.6319	Miscibility	X					
830.6320	Corrosion Characteristics	X					
830.6321	Dielectric Breakdown Voltage	X					
830.7000	pH	X					
830.7050	UV/ Visible Absorption						
830.7100	Viscosity	X					
830.7200	Melting Point						
830.7220	Boiling Point						
830.7300	Density	X					
830.7370	Dissociation Constant						
830.7550	Partition Coefficient						
830.7840	Water Solubility						
830.7950	Vapor Pressure						

Grayed out = data not required

related data

R 310

New products must either: 1) supply the product specific acute toxicity 6 pack data (listed below), or 2) provide a bridging rationale document. The bridging document directs OPP to use a currently registered set of 6 acute toxicity data and label; instead of submitting product specific data.

Guideline No.	Acute toxicity (6 pack) Study Title	Data submitted		Cited	
		Yes	No	Yes	No
870.1100	Acute Oral (LD50)	X			
870.1200	Acute Dermal (LD50)	X			
870.1300	Acute Inhalation (LC50)	X			
870.2400	Acute Eye Irritation	X			
870.2500	Acute Dermal Irritation	X			
870.2600	Dermal Sensitization	X			

waiver Request

Efficacy – which guideline is used depends on the proposed label use

Guideline No.	Study Title	Data submitted		Cited		Comments
		Yes	No	Yes	No	
810.3100	Soil Treatments for Imported Fire Ants					
810.3200	Livestock, Poultry, Fur and Wool-bearing Animal Treatments					
810.3300	Treatments to Control Pests of Humans and Pets					
810.3400	Mosquito, Black Fly, and Biting Midge (Sand Fly) Treatments					
810.3500	Premises Treatments					
810.3600	Structural Treatments					
810.3800	Methods for Efficacy Testing of Termite Baits					



December 15, 2011

U.S. Bank
Government Lockbox 979074
1005 Convention Plaza
SL-MO-C2-GL
St. Louis, MO 63197

RE: Checks for 2011 PRIA Fees; Virbac AH, Inc. (EPA Co. Number 2382)

Dear Sir or Madam:

Please find enclosed two (2) checks numbered **1013436** and **1013437** made out to the Environmental Protection Agency (EPA) which are both in the amount of \$4,807.00. These checks fulfill the financial obligations in support of two amendments, to be registered under the company Virbac AH, Inc. (EPA Company Number 2382) Also attached for reference are copies of the EPA Form 8570-1 with information on the registration of the two products with EPA.

Should you have any questions about this payment, please do not hesitate to contact me via telephone at 682-647-3576 or via e-mail at craig.parks@virbacus.com.

Sincerely,

A handwritten signature in cursive script, appearing to read "Craig Parks".

Craig Parks, MS, DVM
Vice President, Research & Development
Virbac Animal Health, Inc.

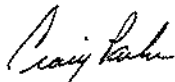


UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

Date: December 20, 2011			EPA Reg. No./File Symbol 2382-TBA		Page 1 of 9
Applicant's/Registrant's Name & Address Virbac AH, Inc. PO Box 162059 Fort Worth TX 76161			Product: EFFIPRO® PLUS TOPICAL SOLUTION FOR DOGS		
Ingredient: Fipronil, Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Product Chemistry Test Guidelines					
830.1550	Product Identity and Composition	New Submission	Virbac AH, Inc.	OWN	
830.1600	Description of Materials Used	New Submission	Virbac AH, Inc.	OWN	
830.1620	Description of Production Process	New Submission	Virbac AH, Inc.	OWN	
830.1650	Description of Formulation Process	New Submission	Virbac AH, Inc.	OWN	
830.1670	Description of Formation of Impurities	New Submission	Virbac AH, Inc.	OWN	
830.1700	5-Batch Analysis	New Submission	Virbac AH, Inc.	OWN	
830.1750	Certified Limits	New Submission	Virbac AH, Inc.	OWN	
830.1800	Analytical Method	New Submission	Virbac AH, Inc.	OWN	
830.6302	Color	New Submission	Virbac AH, Inc.	OWN	
830.6303	Physical State	New Submission	Virbac AH, Inc.	OWN	
830.6304	Odor	New Submission	Virbac AH, Inc.	OWN	
830.6313	Metal Stability		Virbac AH, Inc.	NR	
830.6314	Oxidation/reduction	New Submission	Virbac AH, Inc.	OWN	
830.6315	Flammability	New Submission	Virbac AH, Inc.	OWN	
830.6316	Explosibility		Virbac AH, Inc.	NR	
830.6317	Storage stability	To be conducted	Virbac AH, Inc.	OWN	
Signature 			Name and Title Craig Parks Vice President, Research & Development		Date December 20, 2011

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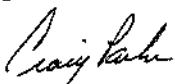
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DATA MATRIX

Date December 20, 2011			EPA Reg. No./File Symbol 2382-TBA	Page 2 of 9	
Applicant's/Registrant's Name & Address Virbac AH, Inc PO Box 162059 Fort Worth TX 76161			Product: EFFIPRO® PLUS TOPICAL SOLUTION FOR DOGS		
Ingredient: Fipronil, Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7100	Viscosity	New Submission	Virbac AH, Inc.	OWN	
830.6319	Miscibility		Virbac AH, Inc.	NR	
830.6320	Corrosion characteristics	To be conducted	Virbac AH, Inc.	OWN	
830.6321	Dielectric breakdown voltage		Virbac AH, Inc.	NR	
830.7000	pH	New Submission	Virbac AH, Inc.	OWN	
830.7300	Density, bulk density, or specific gravity	New Submission	Virbac AH, Inc.	OWN	
830.7320	Particle Size distribution		Virbac AH, Inc.	NR	
40 CFR 158.340 Toxicology Data Requirements					
870.1100	Acute oral toxicity	New Submission	Virbac AH, Inc.	OWN	
870.1200	Acute dermal toxicity	New Submission	Virbac AH, Inc.	OWN	
870.1300	Acute inhalation toxicity	Waiver requested	Virbac AH, Inc.		
870.2400	Primary eye irritation	New Submission	Virbac AH, Inc.	OWN	
870.2500	Primary dermal irritation	New Submission	Virbac AH, Inc.	OWN	
870.2600	Dermal sensitization	New Submission	Virbac AH, Inc.	OWN	
Signature 			Name and Title Craig Parks Vice President, Research & Development		Date December 20, 2011

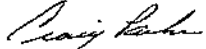
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DATA MATRIX

Date: December 20, 2011			EPA Reg. No./File Symbol: 2382-TBA		Page 3 of 9
Applicant's/Registrant's Name & Address Virbac AH, Inc. PO Box 162059 Fort Worth TX 76161			Product: EFFH*RO® PLUS TOPICAL SOLUTION FOR DOGS		
Ingredient: Fipronil, Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Efficacy and Safety Data					
870.7200	Dog safety	43444905	Merial	OLD	
870.7200	Dog safety	43577711	Merial	OLD	
870.7200	Dog safety	43863802	Merial	OLD	
870.7200	Dog safety	43121110	Merial	OLD	
870.7200	Dog safety	43121111	Merial	OLD	
870.7200	Dog safety	45620507	Merial	PAY	
870.7200	Dog safety	43396408	Ecto Development Corporation	OLD	
870.7200	Dog safety	43612601	Ecto Development Corporation	OLD	
870.7200	Dog safety	44900902	Virbac AH, Inc.	OWN	
870.7200	Dog safety	44900903	Virbac AH, Inc.	OWN	
870.7200	Dog safety	42178309	Sunimoto Chemical Company, Ltd.	OLD	
870.7200	Dog safety	New submission	Virbac AH, Inc.	OWN	
810.3300	Efficacy	43121114	Merial	OLD	
810.3300	Efficacy	43121115	Merial	OLD	
810.3300	Efficacy	43121116	Merial	OLD	
810.3300	Efficacy	43121117	Merial	OLD	
810.3300	Efficacy	43121118	Merial	OLD	
810.3300	Efficacy	43121119	Merial	OLD	
810.3300	Efficacy	43121120	Merial	OLD	
Signature 			Name and Title Craig Parks Vice President, Research & Development		Date December 20, 2011

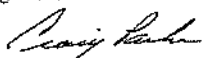


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Applicant's/Registrant's Name & Address Virbac AH, Inc PO Box 162059 Fort Worth TX 76161			Product: EFFIPRO® PLUS TOPICAL SOLUTION FOR DOGS		
Ingredient: Fipronil, Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Efficacy and Safety Data					
810.3300	Efficacy	43121121	Merial	OLD	
810.3300	Efficacy	43121122	Merial	OLD	
810.3300	Efficacy	43444901	Merial	OLD	
810.3300	Efficacy	43577701	Merial	OLD	
810.3300	Efficacy	43577712	Merial	OLD	
810.3300	Efficacy	43577713	Merial	OLD	
810.3300	Efficacy	43951701	Merial	OLD	
810.3300	Efficacy	44088901	Merial	OLD	
810.3300	Efficacy	46006002	Wellmark International	PUBL	
810.3300	Efficacy	44900904	Virbac AH, Inc.	OWN	
810.3300	Efficacy	45020601	Virbac AH, Inc.	OWN	
810.3300	Efficacy	Pending; submitted with Effipro Plus Cat Application		OWN	
810.3300	Efficacy	New submission		OWN	
Signature 			Name and Title Craig Parks Vice President, Research & Development		Date December 20, 2011

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Applicant's/Registrant's Name & Address
Virbac AH, Inc
PO Box 162059
Fort Worth TX 76161

Product:

EFFIPRO® PLUS TOPICAL SOLUTION FOR DOGS

Ingredient: Fipronil, Pyriproxyfen

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
810.3300	Efficacy	44942011	Merial	PAY	
810.3300	Efficacy	44942106	Merial	PAY	
810.3300	Efficacy	45612701	Merial	PAY	
810.3300	Efficacy	45618501	Merial	PAY	
810.3300	Efficacy	45620501	Merial	PAY	
810.3300	Efficacy	45620502	Merial	PAY	
810.3300	Efficacy	45620503	Merial	PAY	
810.3300	Efficacy	45620504	Merial	PAY	
810.3300	Efficacy	45620505	Merial	PAY	
810.3300	Efficacy	45620506	Merial	PAY	
810.3300	Efficacy	45628101	Merial	PAY	
810.3300	Efficacy	45628102	Merial	PAY	
810.3300	Efficacy	45628103	Merial	PAY	
810.3300	Efficacy	45628104	Merial	PAY	
810.3300	Efficacy	45628105	Merial	PAY	
810.3300	Efficacy	45628201	Merial	PAY	
810.3300	Efficacy	45866901	Merial	PAY	
810.3300	Efficacy	45866902	Merial	PAY	
810.3300	Efficacy	46019201	Merial	PAY	
810.3300	Efficacy	46019202	Merial	PAY	

Signature

Name and Title
Craig Parks
Vice President, Research & Development

Date
December
20, 2011

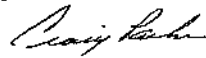
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Applicant's/Registrant's Name & Address Virbac AH, Inc PO Box 162059 Fort Worth TX 76161			Product: EFFIPRO® PLUS TOPICAL SOLUTION FOR DOGS		
Ingredient: Fipronil, Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Child Resistant Packaging					
40 CFR 157	Evaluation of the 3 ml Applicator Tube with 1.34 ml water, 1 applicator tube test for Child-Resistant Effectiveness	48095221	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 3 ml Applicator Tube with 1.34 ml water, 6 applicators tube test for Child-Resistant Effectiveness	48095222	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 3 ml Applicator Tube with 1.34 ml water, 36 applicators tube test for Child-Resistant Effectiveness	48095223	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 3 ml Applicator Tube with 1.34 ml water, 1 applicator tube test for Senior-Use Effectiveness	48095224	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 3 ml Applicator Tube with 1.34 ml water, 6 applicators tube test for Senior-Use Effectiveness	48095225	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 3 ml Applicator Tube with 1.34 ml water, 36 applicators tube test for Senior-Use Effectiveness	48095226	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 3 ml Applicator Tube with 2.68ml water, 1 applicator tube test for Child-Resistant Effectiveness	48095227	Virbac AH, Inc.	OWN	
Signature 			Name and Title Craig Parks Vice President, Research & Development		Date December 20, 2011

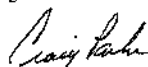


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Date: December 16, 2011			EPA Reg. No./File Symbol 2382-TBA		Page 7 of 9
Applicant's/Registrant's Name & Address Virbac AH, Inc PO Box 162059 Fort Worth TX 76161			Product: EFFIPRO [®] PLUS TOPICAL SOLUTION FOR DOGS		
Ingredient: Fipronil, Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
40 CFR 157	Evaluation of the 3 ml Applicator Tube with 2.68 ml water, 6 applicators tube test for Child-Resistant Effectiveness	48095228	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 3 ml Applicator Tube with 2.68 ml water, 36 applicators tube test for Child-Resistant Effectiveness	48095229	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 3 ml Applicator Tube with 2.68 ml water, 1 applicator tube test for Senior-Use Effectiveness	48095230	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 3 ml Applicator Tube with 2.68 ml water, 6 applicators tube test for Senior-Use Effectiveness	48095231	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 3 ml Applicator Tube with 2.68 ml water, 36 applicators tube test for Senior-Use Effectiveness	48095232	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 6 ml Applicator Tube with 4.02 ml water, 1 applicator tube test for Child-Resistant Effectiveness	48095233	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 6 ml Applicator Tube with 4.02 ml water, 6 applicators tube test for Child-Resistant Effectiveness	48095234	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 6 ml Applicator Tube with 4.02 ml water, 36 applicators tube test for Child-Resistant Effectiveness	48095235	Virbac AH, Inc.	OWN	
Signature 			Name and Title Craig Parks Vice President, Research & Development		Date December 20, 2011

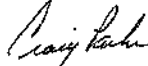
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Applicant's/Registrant's Name & Address Virbac AH, Inc PO Box 162059 Fort Worth TX 76161			Product: EFFIPRO® PLUS TOPICAL SOLUTION FOR DOGS		
Ingredient: Fipronil, Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
40 CFR 157	Evaluation of the 1ml applicator tube with 0.67 ml water, 1 applicator tube test for Child-Resistant Effectiveness	48410001	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 1ml applicator tube with 0.67 ml water, 1 applicator tube test for Senior-Use Effectiveness	48410002	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 1ml applicator tube with 0.67 ml water, 6 applicator tube test for Child-Resistant Effectiveness	48410003	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 1ml applicator tube with 0.67 ml water, 6 applicator tube test for Senior-Use Effectiveness	48410004	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 1ml applicator tube with 0.67 ml water, 36 applicator tube test for Child-Resistant Effectiveness	48410005	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 1ml applicator tube with 0.67 ml water, 36 applicator tube test for Senior-Use Effectiveness	48410006	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 1ml applicator tube with 0.67 ml water, 3 applicator tube test for Child-Resistant Effectiveness	48410007	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 1ml applicator tube with 0.67 ml water, 3 applicator tube test for Senior-Use Effectiveness	48410008	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 3ml applicator tube with 1.34 ml water, 3 applicator tube test for Child-Resistant Effectiveness	48410009	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 3ml applicator tube with 1.34 ml water, 3 applicator tube test for Senior-Use Effectiveness	48410010	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 3ml applicator tube with 2.68 ml water, 3 applicator tube test for Child-Resistant Effectiveness	48410011	Virbac AH, Inc.	OWN	
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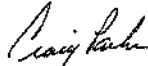


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Applicant's/Registrant's Name & Address Virbac AH, Inc PO Box 162059 Fon Worth TX 76161		Product: EFFIPRO® PLUS TOPICAL SOLUTION FOR DOGS			
Ingredient: Fipronil, (pyriproxyfen)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
40 CFR 157	Evaluation of the 3ml applicator tube with 2.68 ml water, 3 applicator tube test for Senior-Use Effectiveness	48410012	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 1ml applicator tube with 4.02 ml water, 3 applicator tube test for Child-Resistant Effectiveness	48410013	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 1ml applicator tube with 4.02 ml water, 3 applicator tube test for Senior-Use Effectiveness	48410014	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 3ml applicator tube with 2.68 ml water, 1 applicator tube test for Senior-Use Effectiveness	48410015	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 3ml applicator tube with 2.68 ml water, 36 applicator tube test for Senior-Use Effectiveness	48410016	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 6ml applicator tube with 4.02 ml water, 6 applicator tube test for Senior-Use Effectiveness	48410017	Virbac AH, Inc.	OWN	
Signature 			Name and Title Craig Parks Vice President, Research & Development		Date December 20, 2011

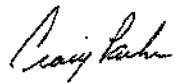


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Applicant's/Registrant's Name & Address Virbac AH, Inc. PO Box 162059 Fort Worth TX 76161		Product: EFFRO® PLUS TOPICAL SOLUTION FOR DOGS			
Ingredient: Fipronil, Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Product Chemistry Test Guidelines					
			Virbac AH, Inc.	OWN	
			Virbac AH, Inc.	OWN	
			Virbac AH, Inc.	OWN	
			Virbac AH, Inc.	OWN	
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			Virbac AH, Inc.	OWN	
			Virbac AH, Inc.	OWN	
			Virbac AH, Inc.	OWN	
			Virbac AH, Inc.	OWN	
			Virbac AH, Inc.	OWN	
			Virbac AH, Inc.	OWN	
			Virbac AH, Inc.	NR	
			Virbac AH, Inc.	OWN	
			Virbac AH, Inc.	OWN	
			Virbac AH, Inc.	NR	
Virbac AH, Inc.	OWN				
Signature 			Name and Title Craig Parks Vice President, Research & Development		Date December 20, 2011

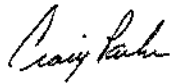


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Applicant's/Registrant's Name & Address Virbac AH, Inc PO Box 162059 Fort Worth TX 76161			Product: EFFIPRO® PLUS TOPICAL SOLUTION FOR DOGS		
Ingredient: Fipronil, Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
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			Virbac AH, Inc.	NR	
			Virbac AH, Inc.	OWN	
			Virbac AH, Inc.	NR	
			Virbac AH, Inc.	OWN	
			Virbac AH, Inc.	OWN	
			Virbac AH, Inc.	NR	
			Virbac AH, Inc.	OWN	
			Virbac AH, Inc.	OWN	
			Virbac AH, Inc.		
			Virbac AH, Inc.	OWN	
			Virbac AH, Inc.	OWN	
			Virbac AH, Inc.	OWN	
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Applicant's/Registrant's Name & Address Virbac AH, Inc PO Box 162059 Fort Worth TX 76161			Product: BFFIPRO® PLUS TOPICAL SOLUTION FOR DOGS		
Ingredient: Fipronil, Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Merial	OLD	
			Merial	OLD	
			Merial	OLD	
			Merial	OLD	
			Merial	OLD	
			Merial	PAY	
			Ecto Development Corporation	OLD	
			Ecto Development Corporation	OLD	
			Virbac AH, Inc.	OWN	
			Virbac AH, Inc.	OWN	
			Sumitomo Chemical Company, Ltd.	OLD	
			Virbac AH, Inc.	OWN	
			Merial	OLD	
			Merial	OLD	
			Merial	OLD	
			Merial	OLD	
			Merial	OLD	
			Merial	OLD	
			Merial	OLD	
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Applicant's/Registrant's Name & Address Virbac AH, Inc PO Box 162059 Fort Worth TX 76161		Product: EFFIPRO® PLUS TOPICAL SOLUTION FOR DOGS			
Ingredient: Fipronil, Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Efficiency and Safety Data					
			Merial	OLD	
			Merial	OLD	
			Merial	OLD	
			Merial	OLD	
			Merial	OLD	
			Merial	OLD	
			Merial	OLD	
			Merial	OLD	
			Merial	PAY	
Signature 			Name and Title Craig Parks Vice President, Research & Development		Date December 20, 2011

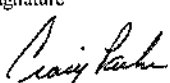
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DATA MATRIX

Date December 20, 2011			EPA Reg. No./File Symbol 2382-TBA		Page 5 of 9
Applicant's/Registrant's Name & Address Virbac AH, Inc P.O. Box 162059 Fort Worth TX 76161			Product: EFFIPRO® PLUS TOPICAL SOLUTION FOR DOGS		
Ingredient: Fipronil, Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MIRID Number	Submitter	Status	Note
			Merial	PAY	
			Merial	PAY	
			Merial	PAY	
			Merial	PAY	
			Merial	PAY	
			Merial	PAY	
			Merial	PAY	
			Merial	PAY	
			Merial	PAY	
			Merial	PAY	
			Merial	PAY	
			Merial	PAY	
			Merial	PAY	
			Merial	PAY	
Signature 			Name and Title Craig Parks Vice President, Research & Development		Date December 20, 2011

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Date: December 20, 2011		EPA Reg. No./File Symbol 2382-TBA		Page 6 of 9	
Applicant's/Registrant's Name & Address Virbac AH, Inc PO Box 162059 Fort Worth TX 76161		Product: EFFIPRO® PLUS TOPICAL SOLUTION FOR DOGS			
Ingredient: Fipronil, Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Child Resistant Packaging					
			Virbac AH, Inc.	OWN	
			Virbac AH, Inc	OWN	
			Virbac AH, Inc.	OWN	
			Virbac AH, Inc	OWN	
			Virbac AH, Inc.	OWN	
			Virbac AH, Inc	OWN	
			Virbac AH, Inc.	OWN	
Signature 			Name and Title Craig Parks Vice President, Research & Development		Date December 20, 2011



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Date: December 16, 2011			EPA Reg. No./File Symbol 2382-TBA		Page 7 of 9
Applicant's/Registrant's Name & Address Virbac AH, Inc PO Box 162059 Fort Worth TX 76161			Product: EFFIPRO® PLUS TOPICAL SOLUTION FOR DOGS		
Ingredient: Fipronil, Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Virbac AH, Inc.	OWN	
			Virbac AH, Inc	OWN	
			Virbac AH, Inc.	OWN	
			Virbac AH, Inc	OWN	
			Virbac AH, Inc.	OWN	
			Virbac AH, Inc	OWN	
			Virbac AH, Inc.	OWN	
			Virbac AH, Inc	OWN	
Signature 			Name and Title Craig Parks Vice President, Research & Development		Date December 20, 2011

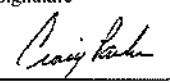
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Ingredient: Fipronil, Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Virbac AH, Inc.	OWN	
			Virbac AH, Inc.	OWN	
			Virbac AH, Inc.	OWN	
			Virbac AH, Inc.	OWN	
			Virbac AH, Inc.	OWN	
			Virbac AH, Inc.	OWN	
			Virbac AH, Inc.	OWN	
			Virbac AH, Inc.	OWN	
			Virbac AH, Inc.	OWN	
			Virbac AH, Inc.	OWN	
			Virbac AH, Inc.	OWN	
Signature 			Name and Title Craig Parks Vice President, Research & Development		Date December 20, 2011

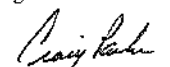
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Ingredient: Fipronil, Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Virbac AH, Inc.	OWN	
			Virbac AH, Inc.	OWN	
			Virbac AH, Inc.	OWN	
			Virbac AH, Inc.	OWN	
			Virbac AH, Inc.	OWN	
			Virbac AH, Inc.	OWN	
Signature 			Name and Title Craig Parks Vice President, Research & Development		Date December 20, 2011

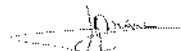


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DATA MATRIX

Date: August 23, 2011			EPA Reg No./File Symbol 87825-R		Page 1 of 6
Applicant's/Registrant's Name & Address Virbac SA 1ere avenue 2065 M - LID F-09516 Carros, France			Product: Fipronil Technical		
Ingredient: Fipronil					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Product Chemistry Test Guidelines					
830.1550	Product Identity and Composition	48095240, 48449201	Virbac.	OWN	
830.1600	Description of Materials Used	48095240	Virbac	OWN	
830.1620	Description of Production Process	48095239	Virbac	OWN	
830.1650	Description of Formulation Process	48095239	Virbac	OWN	
830.1670	Description of Formation of Impurities	48095240, 48449201	Virbac	OWN	
830.1700	Preliminary Analysis	48095241	Virbac	OWN	
830.1750	Certified Limits	48095240, 48449201	Virbac	OWN	
830.1800	Analytical Method	48095242	Virbac	OWN	
830.1900	Submittal of samples		Virbac	N/A	
830.6302	Color	48095240, 48095243	Virbac	OWN	
830.6303	Physical State	48095240, 48095243	Virbac	OWN	
830.6304	Odor	48095243	Virbac	OWN	
830.6313	Accelerated Storage Stability-Metal Ions	48095243	Virbac	OWN	
830.6314	Oxidation/reduction	48095239	Virbac	OWN	
830.6315	Flammability	48095239	Virbac	OWN	
830.6316	Explosibility	48095239	Virbac	NR	
830.6317	1 Yr. Storage Stability		Virbac	OWN	See note page 2
Signature 			Name and Title Jean-Pascal Marc Corporate Product Innovation Director		Date August 23, 2011

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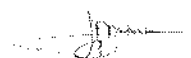
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DATA MATRIX

Date August 23, 2011		EPA Reg No./File Symbol 87825-R		Page 2 of 6	
Applicant's/Registrant's Name & Address Virbac SA 1ere avenue 2065 M - LID F-06516 Carros, France		Product: Fipronil Technical			
Ingredient: Fipronil					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6318	Viscosity		Virbac	N/A	
830.6319	Miscibility		Virbac	N/A	Solid
830.6320	Corrosion characteristics		Virbac	OWN	See note page 2
830.6321	Dielectric breakdown voltage		Virbac	N/A	Waived
830.7000	pH	48095247	Virbac	OWN	
830.7200	Melting Point	48095249	Virbac	OWN	
830.7300	Density bulk density or specific gravity	48095250	Virbac	OWN	
830.7320	Particle Size		Virbac	N/A	
830.7050	UV/Visible Spectrum	48095248	Virbac	OWN	
830.7370	Dissociation constant	48095251	Virbac	OWN	
830.7520;830.7550; 830.7560 830.7570	Octanol/water partition coefficient	48095244	Virbac	OWN	
830.7840;830.7860	Solubility	48095245	Virbac	OWN	
830.7950	Vapor pressure	48095246	Virbac	OWN	
Signature 			Name and Title Jean-Pascal Marc Corporate Product Innovation Director		Date August 23, 2011

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Note: 830.6317 and 830.6320: Per Agency policy, storage stability and corrosion characteristics data are not required to be submitted unless specifically requested by the Agency. Virbac has initiated these studies and will submit the final reports if required when the studies are completed.



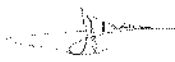
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DATA MATRIX

Date: August 23, 2011		EPA Reg No./File Symbol 87825-R		Page 3 of 6	
Applicant's/Registrant's Name & Address Virbac SA 1ere avenue 2065 M - LLD F-06516 Cannes, France		Product: Fipronil Technical			
Ingredient: Fipronil					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
40 CFR 158.340 Toxicology Data Requirements					
870.1100	Acute oral toxicity	42918628; 43235401 43279706	BASF	OLD	
870.1200	Acute dermal toxicity	42918629	BASF	OLD	
870.1200	Acute dermal toxicity	43235402	BASF	OLD	
870.1300	Acute inhalation toxicity	42918631	BASF	OLD	
870.2400	Primary eye irritation	42918632	BASF	OLD	
870.2500	Primary dermal irritation	42918630	BASF	OLD	
870.2600	Dermal sensitization	42918634	BASF	OLD	
870.6100	Acute delayed neurotoxicity	42918635	BASF	OLD	
870.6100	Acute delayed neurotoxicity	43559501	BASF	OLD	
870.3100	90-day oral toxicity - rodent	42918643	BASF	OLD	
870.3150	90-day oral toxicity - nonrodent	42918642	BASF	OLD	
870.3200	21-day dermal toxicity	42918644	BASF	OLD	
870.3250	90-day dermal toxicity	DATA GAP	BASF	GAP	*See below
870.6100	90-day neurotoxicity - mammal	43291703	BASF	OLD	
81-8	Neurotoxicity to Rats by Acute Oral Administration	44431801	BASF	PAY	
Signature 			Name and Title Jean-Pascal Marc Corporate Product Innovation Director		Date August 23, 2011

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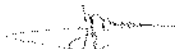
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Date: August 23, 2011		EPA Reg No./File Symbol: 87825-R		Page 4 of 6	
Applicant's/Registrant's Name & Address Virbac SA 1ere avenue 2065 M - LID F-06516 Carros, France		Product: Fipronil Technical			
Ingredient: Fipronil					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
40 CFR 158.340 Toxicology Data Requirements (Continued)					
84-2	Structural chromosomal aberration	42918680	BASF	OLD	
84-2	Structural chromosomal aberration	42918653	BASF	OLD	
84-2	Other genotoxic effects	42918651;42918653 43501703	BASF	OLD	
85-1/870.7485	General metabolism	42918655	BASF	OLD	
85-1/870.7485	General metabolism	43253701	BASF	PAY	
85-1/870.7485	General metabolism	43737308	BASF	OLD	
85-1/870.7485	General metabolism	42918654	BASF	OLD	
85-1/870.7485	General metabolism	42977904	BASF	OLD	
85-1/870.7485	General metabolism	43253701	BASF	OLD	
85-2/870.7600	Dermal penetration	43737308	BASF	PAY	
85-7/870.7600	Immunotoxicity	DATA GAP		GAP	*See below
40 CFR 158.490 Wildlife and Aquatic Organisms Data Requirements					
71-1/850.2100	Avian oral LD 50 – mallard or bobwhite	42918617 42918616	BASF	OLD	
72-1/850.1075	Freshwater fish LC 50 – rainbow or bluegill	42918624;42918673; 42918674;42977902 43279703;43291718	BASF	OLD OLD OLD	
Signature 			Name and Title Jean-Pascal Mare Corporate Product Innovation Director		Date August 23, 2011

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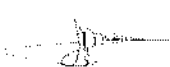
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DATA MATRIX

Date: August 23, 2011			EPA Reg. No./File Symbol 87825-R		Page 5 of 6
Virbac SA 1 ere avenue 2065 M - LID F-06516 Carros, France			Product: Fipronil Technical		
Ingredient: Fipronil					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
83-1/870.4100	Chronic feeding – rodent	42918648	BASF	OLD	
83-1/870.4100	Chronic feeding – nonrodent	42918645	BASF	OLD	
83-1/870.4100	Chronic feeding – nonrodent	43402802	BASF	PAY	
83-2/870.4200	Oncogenicity – mouse	42918649	BASF	OLD	
83-2/870.4200	Oncogenicity – mouse	43501702	BASF	PAY	
83-2/870.4200	Oncogenicity – rat	42918648	BASF	OLD	
83-3/870.3700	Teratogenicity – rabbit	42918646	BASF	OLD	
83-3/870.3700	Teratogenicity – rat	42977903	BASF	OLD	
83-3/870.3700	Teratogenicity – rat	44275001	BASF	PAY	
83-6/870.6300	Developmental neurotoxicity	44039002	BASF	PAY	
83-4/870.3800	Reproduction	42918647	BASF	OLD	
84-2/870.5100	Gene mutation	42918652	BASF	OLD	
84-2/870.5100	Gene mutation	42918679	BASF	OLD	
84-2/870.5100	Gene mutation	43291716	BASF	OLD	
84-2/870.5100	Gene mutation	43291717	BASF	OLD	
84-2/870.5100	Gene mutation	43291721	BASF	OLD	
84-2/870.5100	Gene mutation	43291722	BASF	OLD	
84-2/870.5100	Gene mutation	43401102	BASF	OLD	
Signature 			Name and Title Jean-Pascal Marc Corporate Product Innovation Director		Date August 23, 2011




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Applicant's/Registrant's Name & Address Virbac SA 1ere avenue 2065 M - LID F-06516 Carros, France			Product: Fipronil Technical		
Ingredient: Fipronil					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
72-2/850.1010	Acute LC 50 freshwater invertebrates (<i>Daphnia magna</i>)	42918625	BASF	OLD	
	Acute LC 50 freshwater invertebrates (<i>Daphnia magna</i>)	42918669	BASF	OLD	
	Acute LC 50 freshwater invertebrates (<i>Daphnia magna</i>)	42918671	BASF	OLD	
	Acute LC 50 freshwater invertebrates (<i>Daphnia magna</i>)	43291719	BASF	OLD	
835.2110	Hydrolysis	42977905	BASF	OLD	
40 CFR 158.390 Recentry Protection Data Requirements					
133-3	Dermal exposure - Fipronil	44433302	Merial	PAY	
133-4	Inhalation exposure - Fipronil	44433302	Merial	PAY	
132-1	Dislodgeable residue dissipation - Fipronil	44531203	Merial	PAY	
N/A	Dermal and inhalation exposure of commercial pet groomers (Spot) - Fipronil	44433303	Merial	PAY	
N/A	Analytical method for exposure studies - Fipronil	44433308	Merial	PAY	
Signature 			Name and Title Jean-Pascal Mare Corporate Product Innovation Director		August 23, 2011

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* Pursuant to 40 CFR 152.96 (e), Virbac hereby certifies that Virbac has no basis to believe that this requirement is not a data gap and, further, that Virbac has sent by certified mail to all companies on the current EPA Data Submitters List for fipronil a letter requesting that the company identify, within 60 days of receipt, any valid study that would fulfill this data requirement. Once this 60-day period expires, Virbac will update the Agency us to the information, if any, Virbac receives in response to this "data gap" letter.

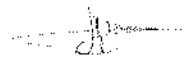


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Applicant's/Registrant's Name & Address Virbac SA 1ere avenue 2065 M - LID F-06516 Carros, France			Product: Fipronil Technical		
Ingredient: Fipronil					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Product Chemistry Test Guidelines					
			Virbac.	OWN	
			Virbac	OWN	
			Virbac	OWN	
			Virbac	OWN	
			Virbac	OWN	
			Virbac	OWN	
			Virbac	OWN	
			Virbac	OWN	
			Virbac	OWN	
			Virbac	N/A	
			Virbac	OWN	
			Virbac	OWN	
			Virbac	OWN	
			Virbac	OWN	
			Virbac	OWN	
			Virbac	NR	
			Virbac	OWN	See note page 2
Signature 			Name and Title Jean-Pascal Marc Corporate Product Innovation Director		Date August 23, 2011

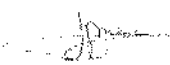


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DATA MATRIX

Date August 23, 2011		EPA Reg No./File Symbol 87825-R		Page 2 of 6	
Applicant's/Registrant's Name & Address Virbac SA 1ere avenue 2065 M - LID F-06516 Carros, France		Product: Fipronil Technical			
Ingredient: Fipronil					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Virbac	N/A	
			Virbac	N/A	Solid
			Virbac	OWN	See note page 2
			Virbac	N/A	Waived
			Virbac	OWN	
			Virbac	OWN	
			Virbac	OWN	
			Virbac	N/A	
			Virbac	OWN	
			Virbac	OWN	
			Virbac	OWN	
			Virbac	OWN	
			Virbac	OWN	
			Virbac	OWN	
Signature 			Name and Title Jean-Pascal Marc Corporate Product Innovation Director		Date August 23, 2011

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Note: 830.6317 and 830.6320: Per Agency policy, storage stability and corrosion characteristics data are not required to be submitted unless specifically requested by the Agency. Virbac has initiated these studies and will submit the final reports if required when the studies are completed.




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Form Approved OMB No. 2070-0060

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WASHINGTON, D.C. 20460

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DATA MATRIX

Date: August 23, 2011		EPA Reg No./File Symbol 87825-R		Page 3 of 6	
Applicant's/Registrant's Name & Address Virbac SA Iere avenue 2065 M - LID F-06516 Carros, France		Product: Fipronil Technical			
Ingredient: Fipronil					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
40 CFR 158.340 Toxicology Data Requirements					
			BASF	OLD	
			BASF	OLD	
			BASF	OLD	
			BASF	OLD	
			BASF	OLD	
			BASF	OLD	
			BASF	OLD	
			BASF	OLD	
			BASF	OLD	
			BASF	OLD	
			BASF	OLD	
			BASF	OLD	
			BASF	GAP	*See below
			BASF	OLD	
	BASF	PAY			
Signature 		Name and Title Jean-Pascal Marc Corporate Product Innovation Director		Date August 23, 2011	




UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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DATA MATRIX

Date: August 23, 2011			EPA Reg No./File Symbol: 87825-R		Page 4 of 6
Applicant's/Registrant's Name & Address Virbac SA 1 rue avenue 2065 M - LID F-06516 Carros, France			Product: Fipronil Technical		
Ingredient: Fipronil					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			BASF	OLD	
			BASF	OLD	
			BASF	OLD	
			BASF	OLD	
			BASF	PAY	
			BASF	OLD	
			BASF	OLD	
			BASF	OLD	
			BASF	PAY	
				GAP	*Sec below
				OLD	
			BASF	OLD	
			BASF	OLD	
			BASF	OLD	
			Signature 		



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DATA MATRIX

Date: August 23, 2011			EPA Reg. No./File Symbol 87825-R		Page 5 of 6
Virbac SA Ire avenue 2065 M - LID F-06516 Carros, France			Product: Fipronil Technical		
Ingredient: Fipronil					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			BASF	OLD	
			BASF	OLD	
			BASF	PAY	
			BASF	OLD	
			BASF	PAY	
			BASF	OLD	
			BASF	OLD	
			BASF	OLD	
			BASF	PAY	
			BASF	PAY	
			BASF	OLD	
			BASF	OLD	
			BASF	OLD	
			BASF	OLD	
			BASF	OLD	
			BASF	OLD	
			BASF	OLD	
			BASF	OLD	
Signature			Name and Title Jean-Pascal Marc Corporate Product Innovation Director		Date August 23, 2011

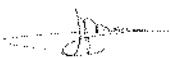


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Date: August 23, 2011			EPA Reg. No./File Symbol 87825-R		Page 6 of 6
Applicant's/Registrant's Name & Address Virbac SA 1ere avenue 2065 M - LID F-06516 Carros, France			Product: Fipronil Technical		
Ingredient: Fipronil					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			BASF	OLD	
			BASF	OLD	
			BASF	OLD	
			BASF	OLD	
			BASF	OLD	
			Merial	PAY	
			Merial	PAY	
			Merial	PAY	
			Merial	PAY	
			Merial	PAY	
			Signature 		

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* Pursuant to 40 CFR 152.96 (c), Virbac hereby certifies that Virbac has no basis to believe that this requirement is not a data gap and, further, that Virbac has sent by certified mail to all companies on the current EPA Data Submitters List for fipronil a letter requesting that the company identify, within 60 days of receipt, any valid study that would fulfill this data requirement. Once this 60-day period expires, Virbac will update the Agency as to the information, if any, Virbac receives in response to this "data gap" letter.

